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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: Sponsored by the Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WHEN: Tuesday, January 25, 2011
9 a.m.–12:30 p.m.

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 732, 734, 740, 772, and 774

[Docket No. 100108014–0121–01]

RIN 0694–AE82

Publicly Available Mass Market Encryption Software and Other Specified Publicly Available Encryption Software in Object Code

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Industry and Security (BIS) is removing from the scope of items subject to the Export Administration Regulations (EAR) "publicly available" mass market encryption object code software with a symmetric key length greater than 64-bits, and "publicly available" encryption object code classified under Export Control Classification Number (ECCN) 5D002 on the Commerce Control List when the corresponding source code meets the criteria specified under License Exception TSU. This change is being made pursuant to a determination by BIS that, because there are no regulatory restrictions on making such software "publicly available," and because, once it is "publicly available," by definition it is available for download by any end user without restriction, removing it from the jurisdiction of the EAR will have no effect on export control policy. This action will not result in the decontrol of source code classified under ECCN 5D002, but it will result in a simplification of the regulatory provisions for publicly available mass market software and specified encryption software in object code.

DATES: This rule is effective: January 7, 2011.

FOR FURTHER INFORMATION CONTACT: For questions of a technical nature, contact: the Information Technology Division, Office of National Security and Technology Transfer Controls at (202) 482–0707 or by e-mail *cpratt@bis.doc.gov.*

For questions of a general nature, contact: Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce at (202) 482–2440 or by e-mail to *scook@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

This rule removes from the jurisdiction of the EAR mass market encryption software and specified encryption object code that is publicly available. Publicly available software, other than encryption software, is not subject to the EAR. Certain publicly available encryption software has remained subject to the jurisdiction of the EAR since the mid-1990s, when commercial items incorporating encryption functionality were transferred to the jurisdiction of the EAR (*see* § 734.3(b)(3) of the EAR). At that time, much less mass market software was "publicly available" than is the case today. Because of the much wider array of "publicly available" mass market and other encryption software in object code, BIS recently reviewed the provisions of the EAR that retained jurisdiction over such software. Pursuant to this review, BIS determined that there are no regulatory restrictions on making such software "publicly available." Moreover, because, once it is "publicly available," it is, by definition, available for download by any end user without restriction, removing it from the jurisdiction of the EAR will have no effect on export control policy. Removing these items from EAR jurisdiction will also result in a simplification of the regulatory provisions. Accordingly, BIS believes that its regulatory discretion should no longer be exercised in a manner that such encryption software remains subject to the EAR.

During its review, BIS noted that the EAR currently provide that making certain encryption software "publicly available" by posting it on the Internet where it may be downloaded by anyone does not establish "knowledge" of a prohibited export or reexport. Additionally, such activity also does not trigger any "red flags" that impose an affirmative duty to inquire under the "Know Your Customer" guidance provided in the EAR (*see* 67 FR 38855, 38857, June 6, 2002). Therefore, a person or company does not violate the EAR if it posts "mass market" encryption software on the Internet for free and anonymous download (*i.e.,* makes it "publicly available"), and the software is downloaded by an anonymous person from anywhere in the world. In addition, if the person or company "publishes" mass market encryption software by another means, the person or company does not violate the EAR.

Through this rule, BIS removes two kinds of encryption software from the jurisdiction of the EAR: (1) Publicly available encryption software in object code with a symmetric key length greater than 64-bits that has been determined to be mass market software under section 742.15(b) of the EAR and has been reclassified under ECCN 5D992; and (2) publicly available encryption software in object code classified under ECCN 5D002 when the corresponding source code meets the criteria specified in section 740.13(e) of the EAR.

Publicly available mass market encryption object code software: Encryption software in object code that has been reviewed by BIS and determined to be mass market software under the section 742.15(b)(3) procedure, or software that does not require review but has been self-classified by the exporter as mass market software under section 742.15(b)(1), is reclassified from Export Control Classification Number (ECCN) 5D002 to ECCN 5D992 on the Commerce Control List (CCL) (Supplement No. 1 to Part 774 of the EAR). ECCN 5D992 software is controlled for anti-terrorism reasons, and requires a license for export to Iran, Cuba, Syria, Sudan and North Korea (Country Group E:1 countries; *see* Supplement No. 1 to Part 740). The procedure to self-classify qualifying mass market software under ECCN 5D992 requires both the submission of an encryption registration to BIS in accordance with section 742.15(b)(7), and the submission of an annual self-classification report in

accordance with section 742.15(c). Meanwhile, for specified software described in section 742.15(b)(3), the procedure to obtain "mass market" classification under ECCN 5D992 requires both the submission of an encryption registration and a classification request to BIS, in accordance with section 742.15(b)(7).

This rule amends the EAR to provide that, once the registration is submitted and the encryption software is properly classified as "mass market" under the relevant requirements of section 742.15(b), if the software is then made "publicly available," it is not subject to the EAR. Software authorized for export and reexport under section 742.15(b)(1) pursuant to registration and self-classification must still be included in the exporter's annual self-classification report for the calendar year during which it was self-classified as "mass market" software.

Publicly available encryption object code corresponding to source code made eligible for License Exception TSU. Section 740.13(e)(1) of the EAR authorizes the export and reexport of encryption object code if both the object code and the source code from which it is compiled would be considered publicly available under section 734.3(b)(3) of the EAR, were they not classified under ECCN 5D002. Section 740.13(e)(3) requires that the source code or the location of the source code be notified to the BIS and to the ENC Encryption Request Coordinator before becoming eligible for License Exception TSU. As with the publicly available mass market encryption software, such object code may be exported to any destination, via anonymous download, without violating the EAR. For the reasons discussed above, BIS's regulatory discretion under the EAR should no longer be exercised in a manner that renders such software subject to the EAR.

Pursuant to section 734.2(b)(9)(ii) of the EAR, publicly available encryption source code that is classified under ECCN 5D002 must be notified to BIS and the ENC Encryption Request Coordinator under the provisions of License Exception TSU (section 740.13(e)). This rule amends this provision to state that the publicly available encryption object code corresponding to publicly available source code eligible for export under section 740.13(e) is no longer subject to the EAR.

In addition, the requirements for encryption registration and classification as described in section 742.15(b) pertain only to "publicly available" mass market encryption software with symmetric key length exceeding 64 bits. "Publicly available" mass market encryption software that does not meet the criterion of "symmetric key length exceeding 64 bits" is not subject to the EAR; neither is any "publicly available" encryption software that is classified under ECCN 5D992 for reasons other than a "mass market" determination. Moreover, several types of mass market encryption software that remain under the jurisdiction of the EAR—even when they are "publicly available"—are no longer subject to encryption registration and classification requirements under section 742.15(b), including, since October 2008, software performing "ancillary cryptography." The removal of the previous classification review requirement demonstrates that there is no regulatory interest in maintaining EAR jurisdiction over these products when they are "publicly available."

The following specific revisions are made to the EAR:

Section 732.2 "Steps Regarding Scope of the EAR"

This rule revises paragraph (b) in section 732.2 and: (1) Replaces the phrase "controlled for EI reasons under ECCN 5D002" with "classified under ECCN 5D002;" (2) replaces the phrase "shall be subject to the EAR" with the phrase "is subject to the EAR;" (3) removes the phrase "and mass market encryption software with symmetric key length exceeding 64-bits classified under ECCN 5D992;" and (4) adds the phrase, "except for publicly available encryption object code software classified under ECCN 5D002 when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR." This revision narrows the scope of publicly available software subject to the EAR to include only encryption source code classified under ECCN 5D002. The sixth sentence of section 732.2 is removed by this rule, as it is redundant.

Part 734 "Scope of the EAR"

This rule removes the phrase "and object code" in the last sentence in paragraph (b)(9)(ii) and adds a new sentence at the end as follows: "Publicly available encryption software in object code that corresponds to encryption source code made eligible for License Exception TSU under section 740.13(e) is not subject to the EAR." In section 734.3, this rule revises paragraph (b)(3) by replacing the phrase "controlled for 'EI' reasons" with "classified" and removing the phrase "and mass market encryption software with symmetric key length exceeding 64-bits controlled under ECCN 5D992." In addition, this rule adds the following sentence to the Note to paragraphs (b)(2) and (b)(3): "Publicly available encryption object code software classified under ECCN 5D002 is not subject to the EAR when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR."

In section 734.7, "Published Information and Software," this rule revises paragraph (c) by adding the modifier "published" before "encryption software," replacing the word "controlled" with "classified," and adding a reference to "Supplement No. 1 to part 774 of the EAR" for the Commerce Control List to add clarity to the first sentence. This rule also adds the phrase "except publicly available encryption object code software classified under ECCN 5D002 when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR," and removes the phrase "and mass market encryption software with symmetric key length exceeding 64-bits controlled under ECCN 5D992" to remove such software from being subject to the EAR for reasons stated in the preamble to this rule. This rule also replaces the word "remain" with the word "remains" in the first sentence of section 734.7 to maintain accurate grammar in the revised sentence. This rule also makes consistent changes to sections 734.8 ("Information resulting from fundamental research") and 734.9 ("Educational information").

This rule amends Supplement No. 1 to part 734 "Questions and Answers—Technology and Software Subject to the EAR" by removing the question and answer to G(3). The question and answer indicated an exception to the published criteria in section 734.7. The exception allowed software to become not subject to the EAR based on being considered published, even if the cost of the software was higher than the cost of reproduction and distribution. The exception required the exporter to request this treatment via a classification request to BIS. As the supplement is guidance, conflicts with regulatory text and no known requests have come in for this treatment, BIS has decided to delete it.

Section 740.13 "Technology and Software—Unrestricted (TSU)"

Section 740.13 is amended by removing the parenthetical phrase "(and corresponding object code)" from the title of paragraph (e), because publicly available corresponding object code is not subject to the EAR if the source code meets the criteria of 740.13(e) and is publicly available. This rule also adds a

phrase to the first sentence of paragraph (e)(1) that reads "subject to the notification requirements of paragraph (e)(3) of this section" to link the notification requirement with the authorization. This rule removes the phrase "without review" in the first sentence of (e)(1), because it is not necessary and may be confusing to state what actions are not required to be eligible for this license exception. The first sentence of (e)(1) is further amended by adding the descriptor "publicly available" in front of "encryption source code," to be more specific about what type of source code is eligible for this license exception. In addition, this rule replaces the phrase "if not controlled by ECCN 5D002, would be considered publicly available under § 734.3(b)(3)" with "is subject to the EAR pursuant to § 734.3(b)(3)" to simplify the first sentence in paragraph (e)(1). For consistency with the change making specified object code not subject to the EAR, this rule removes the last sentence in paragraph (e)(1), which stated "This paragraph also authorizes the export and reexport of the corresponding object code (*i.e.,* that which is compiled from source code that is authorized for export and reexport under this paragraph) if both the object code and the source code from which it is compiled would be considered publicly available under § 734.3(b)(3) of the EAR, if they were not controlled under ECCN 5D002."

Section 772.1 "Definitions of Terms as Used in the EAR"

In section 772.1, the definition of the term "commodity" is amended by removing the last two sentences, because they do not contribute to defining the term "commodity," and the concepts concerning publicly available encryption software can be found in more appropriate parts of the EAR, *e.g.,* Part 734.

ECCN 5D002 "Information Security—Software"

In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5 Telecommunications and "Information Security," Part 2 Information Security, ECCN 5D002 is amended by revising the last note in the License Requirement section by replacing the word "software" with the words "source code," and removing the parenthetical phrase "(and corresponding object code)." This amendment is made to conform the text of the Note to the revisions made by this rule.

Since August 21, 2001, the Export Administration Act has been in lapse. However, the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 12, 2010, 75 FR 50681 (August 16, 2010), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*).

Rulemaking Requirements

1. This final rule has been determined to be significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule involves two collections of information subject to the PRA. One of the collections has been approved by OMB under control number 0694–0088, "Multi Purpose Application," and carries a burden hour estimate of 58 minutes for a manual or electronic submission. The other collection has been approved by OMB under control number 0694–0106, "Reporting and Recordkeeping Requirements under the Wassenaar Arrangement," and carries a burden hour estimate of 21 minutes for a manual or electronic submission. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to OMB Desk Officer, New Executive Office Building, Washington, DC 20503; and to Jasmeet Seehra, OMB Desk Officer, by e-mail at *Jasmeet_K._Seehra@omb.eop.gov* or by fax to (202) 395–7285; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Avenue, NW, Room 6622, Washington, DC 20230.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The Department has determined that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring notice and the opportunity for public comment when such notice and comment is contrary to the public interest. This rule simplifies the regulatory provisions for publicly available mass market software and specified encryption software in object code by removing them from the jurisdiction of the EAR. BIS recognized that there are no regulatory restrictions in making such software "publicly available," and once "publicly available," such software is available for download by any end user without restriction. Thus, removing such "publicly available" items from the jurisdiction of the EAR has no effect on export control policy and clarifies the scope of existing BIS controls. The greater clarity that this rule provides will encourage the exchange of publicly available mass market encryption object code software and certain publicly available encryption object code by the exporting community. In effect, this rule removes any remaining uncertainty in the minds of exporters as to whether their actions constitute violations of U.S. export control law. Thus, delaying the effectiveness of this rule is contrary to the public interest.

For the reasons listed above, good cause exists to waive the 30-day delay in effectiveness otherwise required by the APA. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this direct final rule. Accordingly, no regulatory flexibility analysis is required and none has been prepared. Although notice and opportunity for comment are not required, BIS is issuing this rule in interim final form and is seeking public comments on these revisions.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce, 14th and Pennsylvania Ave., NW., Room 2705, Washington, DC 20230.

List of Subjects

15 CFR Part 732

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research science and technology.

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 772

Exports.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

■ Accordingly, Parts 732, 734, 740, 772, and 774 of the Export Administration Regulations (15 CFR Parts 730 through 774) are amended as follows:

PART 732—[AMENDED]

■ 1. The authority citations for Part 732 continue to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

■ 2. Section 732.2 is amended by revising paragraph (b) to read as follows:

§ 732.2 Steps Regarding Scope of the EAR.

* * * * *

(b) *Step 2: Publicly available technology and software.* This step is relevant for both exports and reexports. Determine if your technology or software is publicly available as defined and explained at part 734 of the EAR. Supplement No. 1 to part 734 of the EAR contains several practical examples describing publicly available technology and software that are outside the scope of the EAR. The examples are illustrative, not comprehensive. Note that encryption software classified under ECCN 5D002 on the Commerce Control List (refer to Supplement No.1 to Part 774 of the EAR) is subject to the EAR even if publicly available, except for publicly available encryption object code software classified under ECCN 5D002 when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR.

* * * * *

PART 734—[AMENDED]

■ 3. The authority citations for Part 734 continue to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010); Notice of November 4, 2010, 75 FR 68673 (November 8, 2010).

■ 4. Section 734.2 is amended in the last sentence of paragraph (b)(9)(ii) by removing the phrase "and object code" and adding a new sentence at the end to read as follows:

§ 734.2 Important EAR terms and principles.

* * * * *

(b) * * *

(9) * * *

(ii) * * * Publicly available encryption software in object code that corresponds to encryption source code made eligible for License Exception TSU under section 740.13(e) is not subject to the EAR.

■ 5. Section 734.3 is amended by:

■ a. Revising paragraph (b)(3) introductory text;

■ b. Adding a new sentence to the end of the Note to paragraphs (b)(2) and (b)(3) to read as follows:

§ 734.3 Items Subject to the EAR.

* * * * *

(b) * * *

(3) Publicly available technology and software, except software classified under ECCN 5D002 on the Commerce Control List, that:

* * * * *

Note to paragraphs (b)(2) and (b)(3) of this section: * * * Publicly available encryption object code software classified under ECCN 5D002 is not subject to the EAR when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR.

* * * * *

■ 6. Section 734.7 is amended by revising paragraph (c) to read as follows:

§ 734.7 Published information and software.

* * * * *

(c) Notwithstanding paragraphs (a) and (b) of this section, note that published encryption software classified under ECCN 5D002 on the Commerce Control List (Supplement No. 1 to part 774 of the EAR) remains subject to the EAR, except publicly available encryption object code software classified under ECCN 5D002 when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR. *See* § 740.13(e) of the EAR for eligibility requirements for exports and reexports of publicly available encryption source code under License Exception TSU.

■ 7. Section 734.8 is amended by revising the last two sentences in paragraph (a) to read as follows:

§ 734.8 Information resulting from fundamental research.

(a) * * * Note that the provisions of this section do not apply to encryption software classified under ECCN 5D002 on the Commerce Control List (Supplement No. 1 to part 774 of the EAR), except publicly available encryption object code software classified under ECCN 5D002 when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR. *See* § 740.13(e) of the EAR for eligibility requirements for exports and reexports of publicly available encryption source code under License Exception TSU.

* * * * *

■ 8. Section 734.9 is amended by revising the last two sentences to read as follows:

§ 734.9 Educational information.

* * * Note that the provisions of this section do not apply to encryption software classified under ECCN 5D002 on the Commerce Control List, except publicly available encryption object code software classified under ECCN 5D002 when the corresponding source code meets the criteria specified in § 740.13(e) of the EAR. *See* § 740.13(e) of the EAR for eligibility requirements for exports and reexports of publicly available encryption source code under License Exception TSU.

Supplement No. 1 to Part 734 [Amended]

■ 8. Supplement No. 1 to part 734 is amended by removing Question G(3) and the answer to G(3).

PART 740—[AMENDED]

■ 9. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

■ 10. Section 740.13 is amended by revising paragraph (e) to read as follows:

§ 740.13 Technology and software—unrestricted (TSU).

* * * * *

(e) *Publicly available encryption source code.* (1) Scope and eligibility. Subject to the notification requirements of paragraph (e)(3) of this section, this paragraph (e) authorizes exports and reexports of publicly available encryption source code classified under

ECCN 5D002 that is subject to the EAR (*see* § 734.3(b)(3) of the EAR). Such source code is eligible for License Exception TSU under this paragraph (e) even if it is subject to an express agreement for the payment of a licensing fee or royalty for commercial production or sale of any product developed using the source code.

(2) *Restrictions.* This paragraph (e) does not authorize:

(i) Export or reexport of any encryption software classified under ECCN 5D002 that does not meet the requirements of paragraph (e)(1), even if the software incorporates or is specially designed to use other encryption software that meets the requirements of paragraph (e)(1) of this section; or

(ii) Any knowing export or reexport to a country listed in Country Group E:1 in Supplement No. 1 to part 740 of the EAR.

(3) *Notification requirement.* You must notify BIS and the ENC Encryption Request Coordinator via e-mail of the Internet location (*e.g.,* URL or Internet address) of the publicly available encryption source code or provide each of them a copy of the publicly available encryption source code. If you update or modify the source code, you must also provide additional copies to each of them each time the cryptographic functionality of the source code is updated or modified. In addition, if you posted the source code on the Internet, you must notify BIS and the ENC Encryption Request Coordinator each time the Internet location is changed, but you are not required to notify them of updates or modifications made to the encryption source code at the previously notified location. In all instances, submit the notification or copy to *crypt@bis.doc.gov* and to *enc@nsa.gov.*

Note to paragraph (e): Posting encryption source code on the Internet (*e.g.,* FTP or World Wide Web site) where it may be downloaded by anyone neither establishes "knowledge" of a prohibited export or reexport for purposes of this paragraph, nor triggers any "red flags" imposing a duty to inquire under the "Know Your Customer" guidance provided in Supplement No. 3 to part 732 of the EAR. Publicly available encryption object code software classified under ECCN 5D002 is not subject to the EAR when the corresponding source code meets the criteria specified in this paragraph (e), *see* § 734.3(b)(3) of the EAR.

* * * * *

PART 742—[AMENDED]

■ 11. The authority citation for part 742 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; Sec 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010); Notice of November 4, 2010, 75 FR 68673 (November 8, 2010).

■ 11. Section 742.15 is amended:

■ a. By revising the fourth sentence of paragraph (b) introductory text; and

■ b. By adding a note to paragraph (b) introductory text to read as follows:

* * * * *

(b) * * * Exports and reexports authorized under paragraphs (b)(1) and (b)(3) of this section (including of mass market encryption software that would be considered publicly available under § 734.3(b)(3) of the EAR) must be supported by an encryption registration in accordance with paragraph (b)(7) of this section and the specific instructions of paragraph (r)(1) of Supplement No. 2 to part 748 of the EAR. * * *

Note to introductory text of paragraph (b): Mass market encryption software that would be considered publicly available under § 734.3(b)(3) of the EAR, and is authorized for export and reexport under this paragraph (b), remains subject to the EAR until the encryption registration and all applicable classification or self-classification requirements set forth in this section are fulfilled.

* * * * *

PART 772—[AMENDED]

■ 11. The authority citation for part 772 continue to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

§ 772.1 [Amended]

■ 12. In § 772.1, the definition of the term "commodity" is amended by removing the last two sentences of the definition.

PART 774—[AMENDED]

■ 13. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.,* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 12, 2010, 75 FR 50681 (August 16, 2010).

■ 14. In Supplement No. 1 to part 774 (the Commerce Control List), Category 5, Part 2, Export Control Classification Number (ECCN) 5D002 is amended by adding the heading "License Requirements" after the ECCN heading and revising the last note in the License Requirements section to read as follows:

Supplement No. 1 to Part 774

* * * * *

5D002 Information Security—"Software as follows (*see* List of Items Controlled)."

License Requirements

* * * * *

Note: Encryption source code classified under this entry remains subject to the EAR even when made publicly available in accordance with part 734 of the EAR. However, publicly available encryption object code software classified under ECCN 5D002 is not subject to the EAR when the corresponding source code meets the criteria specified in § 740.13(e), *see also* § 734.3(b)(3) of the EAR.

* * * * *

Dated: December 20, 2010.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2010–32803 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9513]

RIN 1545–BJ30

Modifications of Debt Instruments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations relating to the modification of debt instruments. The regulations clarify the extent to which the deterioration in the financial condition of the issuer is taken into account to determine whether a modified debt instrument will be recharacterized as an instrument or property right that is not debt. The regulations provide needed

guidance to issuers and holders of debt instruments.

DATES: *Effective Date:* These regulations are effective on January 7, 2011.

Applicability Date: For dates of applicability, see § 1.1001–3(h).

FOR FURTHER INFORMATION CONTACT: Diana Imholtz at (202) 622–3920 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR part 1. On June 4, 2010, a notice of proposed rulemaking (REG–106750–10, 2010–25 IRB 765) was published in the **Federal Register** (75 FR 31736) that proposed amendments to § 1.1001–3 to clarify the circumstances in which the credit quality of the issuer should be considered in determining the nature of the instrument resulting from an alteration or modification of a debt instrument. Because no requests to speak were submitted by August 11, 2010, no public hearing was held. One written comment was received in response to the notice of proposed rulemaking. After consideration of this comment, the proposed regulations are adopted as revised by this Treasury decision. The revisions are discussed in this preamble.

Explanation and Summary of Comments

The only comment received on the proposed regulations requested that the regulations clarify that § 1.1001–3 applies not only to determine whether an exchange of the original debt instrument for a modified instrument has occurred but also to classify the modified instrument resulting from the exchange. The IRS and the Treasury Department intend that Federal income tax principles be used to determine the classification of a modified instrument resulting from an exchange except as specifically provided in § 1.1001–3(f)(7). To avoid doubt on the operation of the rules in the proposed regulations, the final regulations add language to the general rule of § 1.1001–3(b) to make clear that the rules provided in § 1.1001–3(f)(7) apply to determine whether the modified instrument received in an exchange will be classified as debt for Federal income tax purposes. Thus, unless there is a substitution of a new obligor or the addition or deletion of a co-obligor, all relevant factors (for example, creditor rights or subordination) other than any deterioration in the financial condition of the issuer are taken into account in determining whether a modified instrument is properly classified as debt for Federal income tax purposes.

Effective/Applicability Date

The regulations apply to alterations of the terms of a debt instrument on or after January 7, 2011. A taxpayer, however, may rely on § 1.1001–3(f)(7) for alterations of the terms of a debt instrument occurring before that date.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these final regulations is Diana Imholtz, Office of Associate Chief Counsel (Financial Institutions & Products), IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of the Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.1001–3 is amended by:

■ 1. Revising paragraphs (b), (c)(2)(ii), (e)(5)(i) and (h).

■ 2. Adding paragraph (f)(7).

The revisions and addition read as follows:

§ 1.1001–3 Modifications of debt instruments.

* * * * *

(b) *General rule.* For purposes of § 1.1001–1(a), a significant modification of a debt instrument, within the meaning of this section, results in an exchange of the original debt instrument for a modified instrument that differs materially either in kind or in extent. A modification that is not a significant modification is not an exchange for purposes of § 1.1001–1(a). Paragraphs (c) and (d) of this section define the term *modification* and contain examples illustrating the application of the rule. Paragraphs (e) and (f) of this section provide rules for determining when a modification is a significant modification. Paragraph (f) of this section also provides rules for determining whether the modified instrument received in an exchange will be classified as an instrument or property right that is not debt for federal income tax purposes. Paragraph (g) of this section contains examples illustrating the application of the rules in paragraphs (e) and (f) of this section.

(c) * * *

(2) * * *

(ii) *Property that is not debt.* An alteration that results in an instrument or property right that is not debt for Federal income tax purposes is a modification unless the alteration occurs pursuant to a holder's option under the terms of the instrument to convert the instrument into equity of the issuer (notwithstanding paragraph (c)(2)(iii) of this section). The rules of paragraph (f)(7) of this section apply to determine whether an alteration or modification results in an instrument or property right that is not debt.

* * * * *

(e) * * *

(5) *Changes in the nature of a debt instrument*—(i) *Property that is not debt.* A modification of a debt instrument that results in an instrument or property right that is not debt for Federal income tax purposes is a significant modification. The rules of paragraph (f)(7) of this section apply to determine whether a modification results in an instrument or property right that is not debt.

* * * * *

(f) * * *

(7) *Rules for determining whether an alteration or modification results in an instrument or property right that is not debt*—(i) *In general.* Except as provided in paragraph (f)(7)(ii) of this section, the determination of whether an instrument resulting from an alteration or modification of a debt instrument will be recharacterized as an instrument or property right that is not debt for Federal income tax purposes shall take

into account all of the factors relevant to such a determination.

(ii) *Financial condition of the obligor*—(A) *Deterioration in financial condition of the obligor generally disregarded.* Except as provided in paragraph (f)(7)(ii)(B) of this section, in making a determination as to whether an instrument resulting from an alteration or modification of a debt instrument will be recharacterized as an instrument or property right that is not debt, any deterioration in the financial condition of the obligor between the issue date of the debt instrument and the date of the alteration or modification (as it relates to the obligor's ability to repay the debt instrument) is not taken into account. For example, any decrease in the fair market value of a debt instrument (whether or not the debt instrument is publicly traded) between the issue date of the debt instrument and the date of the alteration or modification is not taken into account to the extent that the decrease in fair market value is attributable to the deterioration in the financial condition of the obligor and not to a modification of the terms of the instrument.

(B) *Substitution of a new obligor; addition or deletion of co-obligor.* If there is a substitution of a new obligor or the addition or deletion of a co-obligor, the rules in paragraph (f)(7)(ii)(A) of this section do not apply.

* * * * *

(h) *Effective/applicability date*—(1) *In general.* Except as otherwise provided in paragraph (h)(2) of this section, this section applies to alterations of the terms of a debt instrument on or after September 24, 1996. Taxpayers, however, may rely on this section for alterations of the terms of a debt instrument after December 2, 1992, and before September 24, 1996.

(2) *Exception.* Paragraph (f)(7) of this section applies to an alteration of the terms of a debt instrument on or after January 7, 2011. A taxpayer, however, may rely on paragraph (f)(7) of this section for alterations of the terms of a debt instrument occurring before that date.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: December 21, 2010.

Michael Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–86 Filed 1–6–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–1133]

RIN 1625–AA87

Security Zone; 23rd Annual North American International Auto Show, Detroit River, Detroit, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone on the Detroit River, Detroit, Michigan. This zone is intended to restrict vessels from a portion of the Detroit River in order to ensure the safety of participants, visitors and public officials at the 23rd Annual North American International Auto Show (NAIAS) being held at Cobo Hall in downtown Detroit, MI.

DATES: This rule is effective from 9 a.m. (local) on January 10, 2011, through 10 p.m. (local) on January 23, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2010–1133 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–1133 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail LT Katie Stanko, Prevention Department, Sector Detroit, Coast Guard; telephone (313) 568–9508, e-mail *Katie.R.Stanko@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because delaying this rule would be contrary to the public interest of ensuring the security of the spectators and participants during this event should immediate action be necessary to prevent possible loss of life or property.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring the security of the spectators and participants during this event should immediate action be necessary to prevent possible loss of life or property.

Background and Purpose

This temporary security zone is necessary to ensure the safety of the participants, visitors of the 23rd Annual North American International Auto Show (NAIAS) being held at Cobo Hall in downtown Detroit, MI from possible sabotage or other subversive acts. The public showing days of the NAIAS begin January 15 and extend through January 23. Prior to the public showing, there will also be multiple high profile events; including the press preview days (January 10–11, 2011), industry preview days (January 12–13, 2011), and the charity preview event (January 14, 2011). In 2010, the NAIAS attendance for the public showing was over 650,000 people and industry preview days attracted nearly 16,000 people representing 1,700 companies from 23 countries. Attendance and participation at the 2011 NAIAS is anticipated to rival last year's attendance and will likely be one of the largest media events in North America. Given the expected number of attendees, which includes high-profile visitors, at this event and the recent terrorist threats directed toward the City of Detroit, the Coast Guard is establishing and enforcing a security zone to safeguard the waterways from destruction, loss, or injury from sabotage or other subversive acts.

All persons other than those approved by the Captain of the Port Detroit, or his authorized on-scene representative, are prohibited from entering or moving within this security zone. The Captain of the Port Detroit, or his authorized on-scene representative, may be contacted via VHF Channel 16 for further instructions before transiting through the restricted area. The public will be

made aware of the existence of this security zone and the restrictions involved via Broadcast Notice to Mariners.

Discussion of Rule

A temporary security zone is necessary to ensure the safety of the participants and visitors of the 23rd Annual North American International Auto Show being held at Cobo Hall in downtown Detroit, MI from possible sabotage or other subversive acts. This security zone regulation will be in effect from 9 a.m. on January 10, 2011 through 10 p.m. on January 23, 2011. The zone will be enforced from 9 a.m. to 5 p.m. daily for the duration of the event.

The security zone will encompass an area of the Detroit River encompassed by a line beginning at a point of origin on land adjacent to the west end of Joe Lewis Arena at 42°19.44′ N, 083°03.11′ W; then extending offshore approximately 150 yards to 42°19.39′ N, 083°03.07′ W; then proceeding upriver approximately 2,000 yards to a point at 42°19.72′ N, 083°01.88′ W; then proceeding onshore to a point on land adjacent the Tricentennial State Park at 42°19.79′ N, 083°01.90′ W; then proceeding downriver along the shoreline to connect back to the point of origin. Vessels in close proximity to the security zone will be subject to increased monitoring and boarding. All geographic coordinates are North American Datum of 1983 (NAD 83).

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on scene representative. Entry into, transit, or anchoring within the security zone is prohibited unless authorized by the Captain of the Port Detroit or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. This determination is based on the short time that vessels will be restricted from the area of water impacted by the safety zone. Moreover, vessels may still transit freely in Canadian waters adjacent to the security zone.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the Detroit River, Detroit, Michigan, beginning at a point of origin on land at 42°19.44′ N, 083°03.11′ W; then extending offshore approximately 150 yards to 42°19.39′ N, 083°03.07′ W; then proceeding upriver approximately 2,000 yards to a point at 42°19.72′ N, 083°01.88′ W; then proceeding onshore to a point on land at 42°19.79′ N, 083°01.90′ W; then returning to the point of origin from 9 a.m. January 10, 2011 through 10 p.m. on January 23, 2011.

This security zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This rule will not obstruct the regular flow of commercial traffic and will allow vessel traffic to pass around the security zone. In the event that this temporary security zone affects shipping, commercial vessels may request permission from the Captain of the Port Detroit to transit through the security zone. The Coast Guard will give notice to the public via a Broadcast to Mariners that the regulation is in effect.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedure; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a security zone. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a new temporary section 165.T09–1133 as follows:

§ 165.T09–1133 Security Zone; 23rd Annual North American International Auto Show, Detroit River, Detroit, MI.

(a) *Location.* The following area is a temporary security zone: An area of the Detroit River encompassed by a line beginning at a point of origin on land adjacent to the west end of Joe Lewis Arena at 42°19.44′ N, 083°03.11′ W; then extending offshore approximately 150 yards to 42°19.39′ N, 083°03.07′ W; then proceeding upriver approximately 2,000 yards to a point at 42°19.72′ N, 083°01.88′ W; then proceeding onshore to a point on land adjacent to the Tricentennial State Park at 42°19.79′ N, 083°01.90′ W; then proceeding downriver along the shoreline to connect back to the point of origin on land adjacent to the west end of the Joe Louis Arena. All geographic coordinates are North American Datum of 1983 (NAD 83).

(b) *Effective and enforcement period.* This section is effective from 9 a.m. on January 10, 2011, until 10 p.m. on January 23, 2011. The security zone will be enforced from 9 a.m. to 5 p.m. daily from January 10, 2011, through January 23, 2011.

(c) *Regulations.* (1) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this security zone is prohibited unless authorized by the Captain of the Port Detroit, or his designated on-scene representative.

(2) This security zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Detroit or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the security zone shall contact the Captain of the Port Detroit or his on-scene representative to obtain permission to do so.

(5) Vessel operators given permission to enter or operate in the security zone shall comply with all directions given to them by the Captain of the Port Detroit or his on-scene representative.

Dated: December 23, 2010.

J.E. Ogden,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2011–89 Filed 1–6–11; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 799

[EPA–HQ–OPPT–2007–0531; FRL–8846–9]

RIN 2070–AD16

Testing of Certain High Production Volume Chemicals; Second Group of Chemicals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a final rule under section 4(a)(1)(B) of the Toxic Substances Control Act (TSCA) to require manufacturers, importers, and processors of certain high production volume (HPV) chemical substances to conduct testing to obtain screening level data for health and environmental effects and chemical fate.

DATES: This final rule is effective February 7, 2011. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 7, 2011. For purposes of judicial review, this final rule shall be promulgated at 1 p.m. eastern daylight/standard time on January 24, 2011.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2007–0531. All documents in the docket are listed on the regulations.gov Web site. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC), Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Paul Campanella or John Schaeffer, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone numbers: (202) 564–8091 or (202) 564–8173; e-mail addresses: *campanella.paul@epa.gov* or *schaeffer.john@epa.gov.*

For general information contact: The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process any of the chemical substances that are listed in § 799.5087(j) of the regulatory text. Any use of the term "manufacture" in this document will encompass "import," unless otherwise stated. In addition, as described in Unit VI., once the Agency issues a final rule, any person who exports, or intends to export, any of the chemical substances included in the final rule will be subject to the export notification requirements in 40 CFR part 707, subpart D. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of one or more of the 19 subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.
- Processors of one or more of the 19 subject chemical substances (NAICS codes 325 and 324110), *e.g.,* chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in Unit V.E. and consult § 799.5087(b) of the regulatory text. If you have any questions regarding the applicability of this action to a particular entity, consult either of the technical persons listed under **FOR FURTHER INFORMATION CONTACT**.

II. Background

A. What action is the agency taking?

EPA is promulgating a final test rule under TSCA section 4(a)(1)(B) (15 U.S.C. 2603(a)(1)(B)) that requires manufacturers and processors of 19 chemical substances to conduct testing for environmental fate (including 5 tests for physical/chemical properties and biodegradation); ecotoxicity (in fish, Daphnia, and algae); acute toxicity; genetic toxicity (gene mutations and chromosomal aberrations); repeat dose toxicity; and developmental and reproductive toxicity. The chemical substances are HPV chemicals (i.e., chemical substances with a production/import volume equal to or greater than 1 million pounds (lbs) per year). A detailed discussion regarding efforts to enhance the availability of screening level hazard and environmental fate information about HPV chemicals can be found in a **Federal Register** notice which published on December 26, 2000 (Ref. 1).

In the proposed rule for this final rule, published in the **Federal Register** of July 24, 2008, EPA proposed Screening Information Data Set (SIDS) testing for 19 HPV chemicals (Ref. 2). Comments were received on the proposed rule. In consideration of those comments, EPA changed some testing requirements for certain HPV chemicals, as explained in Unit III. However, none of these changes resulted in dropping all testing proposed for any of the chemical substances, and EPA is still requiring testing for each of the 19 HPV chemicals originally proposed for testing in 2008.

This action also follows an earlier testing action for certain HPV chemicals (see the proposed and final rules entitled "Testing of Certain High Production Volume Chemicals; Proposed Rule" (Ref. 3) and "Testing of Certain High Production Volume Chemicals; Final Rule" (Ref. 4)).

EPA has also proposed testing for a third group of HPV chemicals (Ref. 5), and plans to propose testing for additional HPV chemicals as the Agency learns more about these chemical substances with respect to human exposure, release, and sufficiency of data and experience available on their potential hazards.

B. What is the agency's authority for taking this action?

This final rule is being promulgated under TSCA section 4(a) (15 U.S.C. 2603(a)), which directs EPA to require the development of data relevant to assessing whether activities associated with chemical substances and mixtures present an unreasonable risk of injury to health or the environment, when appropriate findings are made. Section 2(b)(1) of TSCA (15 U.S.C. 2603(b)(1)) states that it is the policy of the United States that:

> * * * adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture [which is defined by statute to include import] and those who process such chemical substances and mixtures[.]

To implement this policy, EPA is promulgating this test rule under TSCA section 4(a)(1)(B) (15 U.S.C. 2603(a)(1)(B)). Section 4(a) of TSCA mandates EPA require by rule that manufacturers and/or processors of

chemical substances and mixtures conduct testing if the EPA Administrator finds that:

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data [.]

If EPA makes these findings for a chemical substance or mixture, the EPA Administrator shall require by rule that testing be conducted on that chemical substance or mixture to develop data about health or environmental effects for which there is an insufficiency of data and experience, and which are relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture, or any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment (TSCA section 4(a)(1)).

Once the EPA Administrator has made a finding under TSCA section 4(a)(1)(A) or TSCA section 4(a)(1)(B), EPA may require any type of health or environmental effects testing necessary to address unanswered questions about the effects of the chemical substance or mixture that are relevant to whether the manufacture, distribution in commerce, processing, use, or disposal of the chemical substance or mixture, or any combination of such activities, presents an unreasonable risk of injury to health or the environment. EPA need not limit the scope of testing required to the factual basis for the TSCA section 4(a)(1)(A)(i) or TSCA section 4(a)(1)(B)(i) findings. This approach is explained in more detail in EPA's TSCA section 4(a)(1)(B) Final Statement of Policy published in the **Federal Register** issue of May 14, 1993 ("B" policy) (Ref. 6, pp. 28738).

In this final rule, EPA is using its broad TSCA section 4(a) authority to obtain data necessary to support the development of preliminary or "screening level" hazard and risk characterizations for certain HPV chemicals specified in Table 2 in § 799.5087(j) of the regulatory text. Following consideration of the public comments received by EPA on the proposed rule (Ref. 2) and production volume information (i.e., 2006 Inventory Update Rule (IUR) data), EPA is making the following findings for the 19 chemical substances under TSCA section 4(a)(1)(B): They are produced in substantial quantities; there is or may be substantial human exposure to them; existing data are insufficient to determine or predict their health and environmental effects; and testing is necessary to develop such data.

C. Why is EPA taking this action?

In April 1998, EPA initiated a national effort to make certain basic information about the environmental fate and potential health and environmental hazards associated with the most widespread chemical substances in commerce available to the public. Mechanisms to collect or, where necessary, develop needed data on U.S. HPV chemicals include the voluntary HPV Challenge Program, certain international efforts (the Organization for Economic Cooperation and Development (OECD) HPV SIDS Program, and the International Council of Chemical Associations (ICCA) HPV Initiative), and TSCA section 4 test rules. The voluntary HPV Challenge Program was created to ensure that a baseline set of data on approximately 2,800 HPV chemicals would be made available to EPA and the public. HPV chemicals are manufactured or imported in amounts equal to or greater than 1 million lbs per year and were first identified for this program through data reported under the 1990 IUR. The SIDS data set sought by the HPV Challenge Program was developed by OECD, of which the United States is a member. The SIDS provides an internationally agreed-upon set of test data for screening HPV chemicals for human and environmental hazards, and assists the Agency and others in making an informed, preliminary judgment about the hazards of HPV chemicals.

The voluntary HPV Challenge Program was designed to make maximum use of scientifically adequate existing test data and to avoid unnecessary and duplicative testing of U.S. HPV chemicals. Therefore, EPA is continuing to participate in the voluntary international efforts, complementary to the voluntary HPV Challenge Program, that are being coordinated by OECD to secure basic hazard information on HPV chemicals in use worldwide, including some of those on the 1990 U.S. HPV chemicals list (Ref. 7). This includes agreements to sponsor a U.S. HPV chemical under either the OECD HPV SIDS Program (Ref. 8), including sponsorship by OECD member countries beyond the United States, or the international HPV Initiative that is being organized by the ICCA (Ref. 9).

Additional details regarding the voluntary HPV Challenge Program and these international efforts were provided in the prior HPV TSCA section 4 rules (Refs. 2–4).

As EPA stated in the first HPV test rule, U.S. data needs that remained unmet in the voluntary HPV Challenge Program or through international efforts could be addressed through TSCA section 4 rulemakings, such as the final test rule promulgated by EPA on March 16, 2006 (Ref. 4). This second final TSCA section 4 HPV SIDS rule addresses the unmet data needs for 19 chemical substances.

EPA intends to make the information collected under the final rule available to the public, other Federal agencies, and any other interested parties on its website (*http://www.epa.gov/chemrtk*) and in the docket for the final rule identified under **ADDRESSES.** As appropriate, this information will be used to ensure a scientifically sound basis for risk assessment/management actions.

D. Why is EPA focusing on HPV chemicals and SIDS testing?

This final rule pertains to HPV chemicals, which EPA determined account for 95% of total chemical production in the United States (Ref. 10, p. 32296). EPA found that, of those HPV non-polymeric organic substances based on 1990 IUR reporting, only 7% had a full set of publicly available and internationally recognized basic screening test data for health and environmental effects (Ref. 11). Of the over 2,800 U.S. HPV chemicals, 43% had no publicly available basic hazard data. For the remaining chemical substances, limited amounts of the data were available. This lack of available hazard data compromises EPA's and others' ability to determine whether these HPV chemicals pose potential risks to human health or the environment, as well as the public's ability to know about the hazards of chemical substances that may be found in their environment, their homes, their workplaces, and the products they buy.

SIDS testing evaluates the following six testing endpoints (Ref. 8):

- Acute toxicity.
- Repeat dose toxicity.
- Developmental and reproductive toxicity.
- Genetic toxicity (gene mutations and chromosomal aberrations).
- Ecotoxicity (studies in fish, Daphnia, and algae).

• Environmental fate (including physical/chemical properties (melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility), photolysis, hydrolysis, transport/distribution, and biodegradation).

Data on the six SIDS endpoints provide a consistent minimum set of information that can be used to help assess the relative risks of chemical substances and whether additional testing or assessment is necessary.

E. How would the data developed under this final rule be used?

EPA will use the data obtained from this final rule to support development of preliminary hazard and risk assessments for the 19 HPV chemicals subject to the rule. The data will also be used by EPA to set priorities for further testing that may produce hazard information on these chemicals that may be needed by EPA, other Federal agencies, the public, industry, and others, to support adequate risk assessments. As appropriate, this information will be used to ensure a scientifically sound basis for risk characterizations and risk management actions. As such, this effort will serve to further the Agency's goal of identifying and controlling human and environmental risks as well as providing greater knowledge and protection to the public. EPA uses data from test rules to support such actions as the risk management decisions and activities under TSCA, development of water quality criteria, Toxic Release Inventory (TRI) listings, and reduction of workplace exposures.

In addition, a key goal of the HPV Challenge Program was making basic health and environmental effects data for HPV chemicals available to the public as part of EPA's "Right to Know" Initiative. A basic premise of the HPV Challenge Program was that the public has a right to know about the hazards associated with chemical substances in their environment. Everyone—including industry, environmental protection groups, animal welfare organizations, government groups, and the general public, among others—can use the data provided through the HPV Challenge Program, and also data collected on HPV chemicals through other means, including TSCA section 4 testing, to make informed decisions related to the human and the environmental hazards of chemical substances that they encounter in their daily lives.

III. Response to Public Comments

EPA received a number of comments in response to the proposed rule (Ref. 2). A summary of those comments and EPA's response to each comment are presented in the document entitled "Response to Public Comments" (Ref. 12). The comments and EPA's "Response to Public Comments" document are available in the docket. The comments on the proposed rule were submitted by the Acetaldehyde Working Group (AWG) of the Vinyl Acetate Council; Albemarle Corporation (Albemarle); American Chemistry Council (ACC); Chlorinated Paraffins Industry Association (CPIA); Dyno Nobel, Inc. (Dyno Nobel); and Vertellus Specialties, Inc. (Vertellus). Comments were also submitted by People for the Ethical Treatment of Animals (PETA), the Physicians Committee for Responsible Medicine (PCRM), the Alternatives Research Development Foundation (ARDF), and the American Anti-Vivisection Society (AAVS). Additional comments submitted by PCRM were also on behalf of the Doris Day Animal League (DDAL) and the Humane Society of the United States (HSUS). EPA also received comments from numerous private citizens. In response to these comments, EPA made the following changes to the regulatory text in the final rule:

1. The screening test for reproduction/developmental toxicity is not required for 2,4-hexadienoic acid, (*E,E*)- (Chemical Abstract Service Registry Number (CASRN) 110–44–1), also known as sorbic acid. This change is further discussed in Unit VII.A. and in the "Response to Public Comments" document (Ref. 12).

2. Screening testing for reproductive/developmental toxicity is not required for ethanedioic acid (CASRN 144–62–7). This change is further discussed in Unit VII.B. and in the "Response to Public Comments" document (Ref. 12).

3. Vapor pressure, water solubility, *n*-Octanol/Water Partition Coefficient (log 10 basis) or "log K_{ow}," and aquatic toxicity testing are not required for castor oil, oxidized (CASRN 68187–84–8). EPA is also not requiring water solubility or log K_{ow} testing for castor oil, sulfated, sodium salt (CASRN 68187–76–8). These changes are further discussed in Unit VII.C. and in the "Response to Public Comments" document (Ref. 12). In addition, for castor oil, oxidized (CASRN 68187–84–8), the acute mammalian toxicity test is not required. This change is further discussed in Unit VII.D. and in the "Response to Public Comments" document (Ref. 12).

4. Boiling point is not required for benzenediamine, ar,ar-diethyl-ar-methyl—(CASRN 68479–98–1). This change is further discussed in Unit VII.E. and in the "Response to Public Comments" document (Ref. 12).

5. Acute mammalian toxicity, repeated-dose toxicity, and *in vitro* mutagenicity tests are not required for alkenes, $C_{12–24}$, chloro. These changes are further discussed in Unit VII.F. and in the "Response to Public Comments" document (Ref. 12).

IV. Findings

A. What is the basis for EPA's final rule to test these chemical substances?

As indicated in Unit II.B., in order to promulgate a rule under TSCA section 4(a) requiring the testing of chemical substances or mixtures, EPA must, among other things, make certain findings regarding either risk (TSCA section 4(a)(1)(A)(i)) or production combined with either chemical release or human exposure (TSCA section 4(a)(1)(B)(i)), with regard to those chemical substances. EPA is requiring testing of the chemical substances included in this final test rule based on its findings under TSCA section 4(a)(1)(B)(i) relating to "substantial" production and "substantial human exposure," as well as findings under TSCA section 4(a)(1)(B)(ii) and (iii) relating to sufficient data and the need for testing. The chemical substances included in this final rule are listed in Table 2 in § 799.5087(j) of the regulatory text along with their CASRN.

"Substantial production" of a chemical substance or mixture under TSCA section 4(a)(1)(B)(i) is generally considered to be aggregate production (including import) volume equaling or exceeding 1 million lbs per year of that chemical substance or mixture and exposure of 1,000 workers or more on a routine or episodic basis to a chemical substance or mixture is considered to be "substantial exposure." See EPA's "B" policy (Ref. 6) for further discussion on how EPA generally evaluates chemical substances or mixtures under TSCA section 4(a)(1)(B)(i).

EPA finds that, under TSCA section 4(a)(1)(B)(i), each of the 19 chemical substances included in this final rule is produced in "substantial" quantities and that there is or may be "substantial human exposure" to each chemical substance (Ref. 13). Also, for three substances, EPA finds that, under TSCA section 4(a)(1)(B)(i), the substance enters or may reasonably be anticipated to enter the environment in substantial quantities (Ref. 13). In addition, under TSCA section 4(a)(1)(B)(ii), EPA finds that there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, processing, or use of these chemical

substances, or of any combination of such activities, on human health or the environment. EPA also finds that testing the 19 chemical substances identified in this final rule is necessary to develop such data (TSCA section 4(a)(1)(B)(iii)) (see Unit IV.F.). EPA has not identified any "additional factors" as discussed in the "B" policy (Ref. 6) to cause the Agency to use decisionmaking criteria other than the general thresholds described in the "B" policy with respect to the chemical substances included in this final rule.

The chemical substances included in this final rule are listed in § 799.5087(j) of the regulatory text along with their CASRN. For a chemical-by-chemical summary of each of the findings, see Table 1 of this unit.

TABLE 1—EXPOSURE-BASED FINDINGS

CASRN	2006 IUR production volume (lbs)	Meet exposure based criteria for Mfg & industrial workers	NOES (number of workers)	Meet exposure-based criteria for commercial workers	Meet exposure-based criteria for consumers	Meet substantial or significant release criteria	NLM household chemicals database
75–07–0	> 100 M–500 M	X	216,533		X	X	X
78–11–5	> 1 M–10 M	X	2,650		X		
84–65–1	> 10 M–50 M	X	6,187	X	X		
89–32–7	> 1 M–10 M	X	1,926				
110–44–1	> 1 M–10 M	X	69,243	X	X		X
118–82–1	> 1 M–10 M	X	120,009	X	X		
119–61–9	> 1 M–10 M	X	41,516	X	X		X
144–62–7	> 1 M–10 M	X	142,000	X	X	X	X
149–44–0	> 1 M–10 M	X	239,465	X	X		
2524–04–1	> 10 M–50 M	X	1,088				
4719–04–4	> 10 M–50 M	X	225,251	X	X	X	X
6381–77–7	> 1 M–10 M	X	19,468				
31138–65–5	> 1 M–10 M	X	74,165	X	X		
66241–11–0	> 1 M–10 M	X	38,555	X	X		
68187–76–8	> 1 M–10 M	X	11,164	X	X		
68187–84–8	> 1 M–10 M	X	36,381	X	X		X
68479–98–1	> 10 M–50 M	X	4,121				
68527–02–6	> 1 M–10 M	X	84,192				
68647–60–9	> 1 Billion	X	1,257				

Notes: CASRN—Chemical Abstract Service Registry Number, IUR—Inventory Update Rule, M—Million, Mfg—Manufacturing, NOES—National Occupational Exposure Survey, NLM—National Library of Medicine.

B. Are these chemical substances produced and/or imported in substantial quantities?

EPA finds that each of the chemical substances included in this final rule is produced and/or imported in an amount equal to or greater than 1 million lbs per year (Ref. 13), based on information gathered pursuant to the 2006 IUR (40 CFR part 710), which is the most recently available compilation of TSCA Chemical Substance Inventory data. EPA believes that these annual production and/or importation volumes are "substantial" as that term is used with reference to production in TSCA section 4(a)(1)(B)(i) (see Ref. 6, p. 28746). A discussion of EPA's "substantial production" finding for each chemical substance included in this final rule is contained in a separate document (Ref. 13).

C. Are a substantial number of workers exposed to these chemical substances?

EPA finds that the manufacture, processing, and use of the 19 chemical substances included in this action result or may result in exposure of a substantial number of workers to the chemical substances. These chemical substances are used in a wide variety of industrial applications which result in potential exposures to workers, as described in the exposure support document for this final rule (Ref. 13).

This finding is based, in large part, on information submitted in accordance with the 2006 IUR. For chemicals whose total production volume (manufactured and imported) exceeded 300,000 lbs at a site during calendar year 2005, manufacturers and importers were required to report the number of potentially exposed workers during industrial processing and use to the extent the information was readily obtainable. In addition, the submitters were required to provide information regarding the commercial and consumer uses of the chemical substance.

In accordance with the Agency's "B" policy (Ref. 6), EPA believes, as a general matter, that an exposure of over 1,000 workers to a chemical substance is "substantial" as that term is used with reference to "human exposure" in TSCA section 4(a)(1)(B)(i). EPA further believes, based on experience gained through case-by-case analysis of existing chemicals, that an exposure of 1,000 workers or more to a chemical substance is a reasonable interpretation of the phrase "substantial human exposure" in TSCA section 4(a)(1)(B)(i) (*see* Ref. 6). EPA is not aware of any facts in this case that warrant departure from this policy, and finds that there is or may be substantial human exposure (workers) to these 19 chemical substances.

Besides the 2006 IUR data, EPA also reviewed National Occupational Exposure Survey (NOES) data developed by the National Institute for Occupational Safety and Health (NIOSH). The NOES data additionally support EPA's finding that more than 1,000 workers are exposed to each of the 19 chemical substances that are the subject of this final rule. The NOES was a nationwide data gathering project conducted by NIOSH, which was designed to develop national estimates for the number of workers potentially exposed to various chemical, physical, and biological agents and describe the distribution of these potential exposures. Begun in 1980 and completed in 1983, the survey involved a walk-through investigation by trained surveyors of 4,490 facilities in 523 different types of industries. Surveyors recorded potential exposures when a chemical agent was likely to enter or contact the worker's body for a minimum duration. These potential

exposures could be observed or inferred. Information from these representative facilities was extrapolated to generate national estimates of potentially exposed workers for more than 10,000 different chemical substances (Refs. 14–16). EPA also compared production volumes from the 1986 IUR data collection to the production volumes for the 2006 IUR data collection. Of the 19 chemical substances in this final rule, only one chemical's (acetaldehyde, CASRN 75–07–0) production volume decreased from 1986 to 2006 (Ref. 13). The 2006 IUR production volume data are consistent with NOES results, as the production volumes for the remaining chemical substances either stayed the same or increased since 1986, thereby indicating that the usage of these chemical substances is no less than when NOES data were gathered.

EPA has performed a chemical-by-chemical analysis for all 19 chemical substances and carefully considered the industrial process and use information along with the commercial and consumer use information from the 2006 IUR submissions. Commercial uses are defined as "The use of a chemical substance or mixture in a commercial enterprise providing saleable goods or services (*e.g.,* dry cleaning establishment, painting contractor)" (40 CFR 710.43). Detailed information from the 2006 IUR submissions can be found in "Testing of Certain High Production Volume Chemicals; Second Group of Chemicals (Exposure Findings Supporting Information)" (Ref. 13). Based on the nature of the IUR uses, EPA considers that chemical substances with reported commercial uses may result in potential exposure to 1,000 workers or more. The total number of workers reported under the 2006 IUR is the sum of information on both industrial workers plus commercial use workers.

In 2003, EPA partially exempted certain petroleum process streams (including "Hydrocarbons, C>4" (CASRN 68647–60–9) and "Oils, reclaimed" (CASRN 69029–75–0)) from reporting certain processing and use data under the TSCA section 8(a) 2006 IUR. The exemption was not based on an assessment of the toxicity of the process streams but on the fact that the chemical substances are frequently processed, transported, and stored in vessels that minimize the potential for releases and exposure to workers (Refs. 17 and 18). Despite the fact that the degree of exposure is expected to be diminished to particular workers because of the chemical processing and handling practices used, available data indicate that more than 1,000 workers are potentially exposed to these chemical substances, supporting the finding of substantial human exposure (Ref. 13).

D. Are a substantial number of consumers exposed to these chemical substances?

Based on 2006 IUR data, EPA finds that the uses of 13 of the chemical substances included in this action result or may result in exposure to a substantial number of consumers (Ref. 13). EPA reviewed the consumer use information reported for the 2006 IUR and carefully considered the nature of those uses. Upon completion of the review, EPA concluded that the reported consumer uses for these 13 chemical substances may result in at least 10,000 potentially exposed consumers, thus meeting the exposure based finding for consumers.

In addition to findings made based on the 2006 IUR data, EPA has also made consumer exposure based findings based on the National Library of Medicine (NLM) Household Products Database (see Ref. 13). The chemical substances reported in the NLM Household Products Database are present in multiple household products subject to TSCA including hobby/craft products, personal care products, home cleaning products, home maintenance products, and automotive products. The NLM Household Products Database provides information on the chemical ingredients and their percentage in specific brands of household products. Information in the NLM Household Products Database is from a variety of publicly available sources including brand-specific labels and Material Safety Data Sheets when available from manufacturers and manufacturers' Web sites.

EPA believes that use of the consumer products identified in the NLM Household Products Database may expose a substantial number of consumers (i.e., greater than 10,000) to these chemical substances. EPA believes that an exposure of over 10,000 consumers to a chemical substance is "substantial" as that term is used with reference to "human exposure" in TSCA section 4(a)(1)(B)(i). EPA further believes, based on experience gained through case-by-case analysis of existing chemical substances, that an exposure of 10,000 consumers or more to a chemical substance is a reasonable interpretation of the phrase "substantial human exposure" in TSCA section 4(a)(1)(B)(i) (*see* Ref. 6). Therefore, EPA finds that there is or may be substantial human exposure (consumers) to these chemical substances.

A discussion of EPA's "substantial exposure" finding for consumers is contained in a separate document (*see* Ref. 13).

E. Are substantial quantities of these chemical substances released to the environment?

EPA finds for three chemical substances in this final rule that there are substantial releases to the environment. One substance, acetaldehyde (CASRN 75–07–0) is included in TRI and has estimated environmental release in 2005 of 13,567,452 lbs (*see* Ref. 13). TRI contains information about releases of certain chemical substances and management of wastes at a wide variety of sources, including manufacturing operations, certain service businesses, and Federal facilities. Two additional chemical substances (ethanedioic acid (CASRN 144–62–7) and 1,3,5-triazine-1,3,5(2H,4H,6H)-triethanol (CASRN 4719–04–4)) also meet the substantial release criteria based on the environmental releases from their reported 2006 IUR uses.

EPA believes that in general an environmental release of a chemical substance in an amount equal to or greater than 1 million lbs per year or greater than 10% of the reported production volume is "substantial" as that term is used with reference to "enter the environment in substantial quantities" in TSCA section 4(a)(1)(B)(i) (*see* Ref. 6).

A discussion of EPA's "substantial release to the environment" finding is contained in a separate document (*see* Ref. 13).

F. Do sufficient data exist for these chemical substances?

EPA has determined that for the 19 chemical substances for which testing is required under this final rule, there are either no data available on SIDS testing endpoints or these data are insufficient to reasonably determine or predict the effects on human health or the environment that may result from exposures to the chemical substances included in this final rule during the manufacturing, processing, or use of the subject chemical substances.

The finding for insufficient data is based on the results of searches for data on SIDS endpoints by EPA, including available data as summarized on its High Production Volume Information System (HPVIS) (Refs. 2, 19, and 20). This finding is also based on the results of EPA's review of studies/data identified by commenters in response to the proposal or identified by EPA after the publication of the proposal to this

final rule. The studies and data submitted or identified subsequent to the proposal were found to be sufficient for some proposed tests of certain chemical substances and those tests are not required for those chemical substances in this final rule (see Unit VII.).

EPA encouraged the submission of existing data on SIDS testing endpoints which are relevant to characterizing the hazard of those chemical substances for which testing was proposed. All such submitted information was carefully evaluated by EPA in the development of the final testing requirements in this rule. However, if persons required to test under this final rule become aware of additional relevant scientifically adequate existing data (including structure-activity relationships (SAR) information or a scientifically defensible category approach) and submit this information to EPA at any time before testing is initiated, the Agency would consider such data to determine if they satisfy the testing requirement and would take appropriate necessary action to ensure that the testing in this rule is no longer required. In fact, they may submit such information as a requested modification to the testing requirements under 40 CFR 790.55 at anytime as long as the request is made at least 60 days before the reporting deadline for the test in question.

Section 799.5087(j) of the regulatory text lists each chemical substance and the SIDS tests for which adequate data are not currently available to the Agency. The Agency finds that the existing data for one or more of the SIDS testing endpoints for each of the chemical substances listed in Table 2 in § 799.5087(j) of the regulatory text (including environmental fate (comprising five tests for physical/chemical properties [melting point, boiling point, vapor pressure, n-octanol/water partition coefficient, and water solubility] and biodegradation); ecotoxicity (tests in fish, Daphnia, and algae); acute toxicity; genetic toxicity (gene mutations and chromosomal aberrations); repeat dose toxicity; and developmental and reproductive toxicity) are insufficient to enable EPA to reasonably determine or predict the human health and environmental effects resulting from manufacture, processing, and use of these chemical substances.

G. Is testing necessary for these chemical substances?

As discussed in Unit II.D., data on SIDS testing endpoints, including acute toxicity, repeat dose toxicity, developmental and reproductive toxicity, genetic toxicity (gene mutations and chromosomal aberrations), ecotoxicity (tests in fish, Daphnia, and algae), and environmental fate (five tests for physical/chemical properties [melting point, boiling point, vapor pressure, *n*-octanol/water partition coefficient, and water solubility] and biodegradation), are necessary in ascertaining the health and environmental effects of the 19 chemical substances in this final rule. EPA knows of no other means to generate the SIDS data other than the testing described in this rule, and therefore believes that conducting the needed SIDS testing identified for the 19 subject chemical substances is necessary to provide data relevant to a determination of whether the manufacture, processing, and use of the chemical substances does or does not present an unreasonable risk of injury to human health and the environment. EPA also believes it is important to make these data available to satisfy the "Right-to-Know" principles included in the HPV Challenge Program goals.

V. Final Rule

A. What testing is being required in this action?

EPA is requiring specific testing and reporting requirements for the chemical substances specified in § 799.5087(j) of the regulatory text. The testing requirements for each chemical are denoted by alphanumeric symbols in Table 2 in § 799.5087(j) of the regulatory text. Table 3 in § 799.5087(j) of the regulatory text provides the key to identify the tests denoted by the alphanumeric symbols and lists special conditions which might apply when conducting some of those tests. The test methods listed in Table 3 in § 799.5087(j) of the regulatory text are grouped according to the endpoint that they address. The following endpoints and test standards are required under this final rule; also discussed in this unit are the special conditions which EPA has identified and is requiring for several of the required test standards.

1. Physical/Chemical Properties

Melting Point: American Society for Testing and Materials (ASTM) E 324–99 (capillary tube) (Ref. 21). (If a Freezing Point: OECD102 (melting point/melting range) (Ref. 25)).

Boiling Point: ASTM E 1719–05 (ebulliometry) (Ref. 22).

Vapor Pressure: ASTM E 1782–08 (thermal analysis) (Ref. 23).

n-Octanol/Water Partition Coefficient: Method A (40 CFR 799.6755—shake flask).

Method B (ASTM E 1147–92 (Reapproved 2005)—liquid chromatography) (Ref. 24).

Method C (40 CFR 799.6756—generator column).

Water Solubility: Method A (ASTM E 1148–02 (Reapproved 2008)—shake flask) (Ref. 26).

Method B (40 CFR 799.6784—shake flask).

Method C (40 CFR 799.6784—column elution).

Method D (40 CFR 799.6786—generator column).

EPA is requiring, for those chemical substances for which melting points determinations are needed, that melting points be determined according to the method ASTM E 324–99. ASTM has explained that ASTM E 324–99 was withdrawn because:

> The standard utilizes old, well-developed technology; it is highly unlikely that any additional [changes] and/or modifications will ever be pursued by the E15 [committee]. The time and effort needed to maintain these documents detract from the time available to develop new standards which use modern technology. (Ref. 27).

However, ASTM still makes the method available for informational purposes and it can still be purchased from ASTM at the address listed in § 799.5087(h) of the regulatory text.

EPA concludes that ASTM's withdrawal of ASTM E 324–99 does not have negative implications on the validity of the method; therefore, EPA is requiring, for those chemical substances for which melting points determinations are needed, that melting points be determined according to the method ASTM E 324–99.

However, EPA received public comment about testing a substance that is a liquid at room temperature (Ref. 12). In its response, EPA notes that the melting point ideally is identical with the solidification or freezing point. Therefore, a measured freezing point would in this case meet the obligation to report the melting point. Since ASTM E 324–99 (capillary tube) does not specifically include instructions for determining freezing point, EPA is instead requiring, for substances which are liquid at room temperature, OECD 102 (melting point/melting range), which includes guidance for determining freezing point.

For the vapor pressure endpoint, ASTM has updated and revised its test method for vapor pressure (ASTM E 1782–08—thermal analysis) since the time of the proposed rule. Some material related to alternative test methods and some unnecessary descriptive material was omitted in the revision, but the test method itself is unchanged. The updated and revised method (ASTM E 1782–08) is listed as the required test method for the vapor pressure endpoint in this final rule. Note: ASTM issues its test methods under a fixed designation (*e.g.,* E1719);

"the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (e) indicates an editorial change since the last revision or reapproval" (Ref. 22).

In addition, ASTM has updated its test method for Measurement of Aqueous Solubility (ASTM E 1148–02). The test method was reapproved in 2008. There was a minor change in "Referenced Documents," but the test method itself is unchanged. When required, the updated method (ASTM E 1148–02 (Reapproved 2008)) is listed as the required test method for the "Water Solubility" endpoint in this final rule (Ref. 26).

For the log K_{ow} and water solubility endpoints, EPA is requiring that certain "special conditions" be considered by test sponsors in determining the appropriate test method that would be used from among those included for these endpoints in Table 3 in § 799.5087(j) of the regulatory text.

For the log K_{ow} endpoint, EPA is requiring that an appropriate selection be made from among three alternative methods for measuring the chemical substance's log K_{ow}. Prior to determining the appropriate standard to use, if any, to measure the n-octanol/water partition coefficient, EPA is recommending that the log K_{ow} be quantitatively estimated. EPA recommends that the method described in "Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients" (Ref. 28) be used in making such estimation. EPA is requiring that test sponsors must submit with the final study report the underlying rationale for the test standard selected for this endpoint. EPA is requiring this approach in recognition of the fact that depending on the chemical substance's log K_{ow}, one or more test methods may provide adequate information for determining the log K_{ow}, but that in some instances one particular test method may be more appropriate. In general, EPA believes that the more hydrophobic a subject chemical substance is, Method B (ASTM E 1147–92 (Reapproved 2005)) and especially Method C (40 CFR 799.6756—generator column) become more suitable than Method A (40 CFR 799.6755—shake flask). The required test methodologies have been developed to meet a wide variety of needs and, as such, are silent on experimental conditions related to pH. Therefore, EPA highly recommends that all required n-octanol/water partition coefficient tests be conducted at pH 7 to ensure environmental relevance. The required test standards and log K_{ow} ranges that would determine which tests must be conducted for this endpoint are shown in Table 2 of this unit.

TABLE 2—TEST REQUIREMENTS FOR THE PHYSICAL/CHEMICAL PROPERTIES

Testing category	Test requirements and references	Special conditions
Physical/chemical properties	*n*-Octanol/water partition coefficient (log 10 basis) or log K_{ow}: The appropriate log K_{ow} test, if any, would be selected from those listed in this column—see Special Conditions in the adjacent column Method A: 40 CFR 799.6755 (shake flask). Method B: ASTM E 1147–92 (Reapproved 2005) (liquid chromatography) Method C: 40 CFR 799.6756 (generator column).	*n*-Octanol/water partition coefficient (log 10 basis) or log K_{ow}: Which method is required, if any, is determined by the test substance's estimated log K_{ow} as follows: log K_{ow} <0: No testing required. log K_{ow} range 0–1: Method A or B. log K_{ow} range > 1–4: Method A, B, or C. log K_{ow} range > 4–6: Method B or C. log K_{ow} >6: Method C. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7.

Note: ASTM—American Society for Testing and Materials.

For the "Water Solubility" endpoint, EPA is requiring that the appropriate selection be made from among four alternative methods for measuring that endpoint. The test method used, if any, would be determined by first quantitatively estimating the test substance's water solubility. One recommended method for estimating water solubility is described in "Improved Method for Estimating Water Solubility from Octanol/Water Partition Coefficient" (Ref. 29). EPA is also requiring that test sponsors submit in the final study report the underlying rationale for the test standard selected for this endpoint. The required test methodologies have been developed to meet a wide variety of needs and, as such, are silent on experimental conditions related to pH. Therefore, EPA highly recommends that all required water solubility tests be conducted starting at pH 7 to ensure environmental relevance. The estimated water solubility ranges that EPA is requiring for use in this final rule to select the appropriate test standard are shown in Table 3 of this unit.

TABLE 3—TEST REQUIREMENTS FOR THE WATER SOLUBILITY ENDPOINT

Testing category	Test requirements and references	Special conditions
Physical/chemical properties	Water solubility:	Water solubility:

TABLE 3—TEST REQUIREMENTS FOR THE WATER SOLUBILITY ENDPOINT—Continued

Testing category	Test requirements and references	Special conditions
	The appropriate method to use, if any, to test for water solubility would be selected from those listed in this column—see Special Conditions in the adjacent column. Method A: ASTM E 1148–02 (Reapproved 2008) (shake flask). Method B: 40 CFR 799.6784 (shake flask). Method C: 40 CFR 799.6784 (column elution). Method D: 40 CFR 799.6786 (generator column).	Which method is required, if any, would be determined by the test substance's estimated water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7. > 5,000 mg/L: Method A or B. > 10 mg/L—5,000 mg/L: Method A, B, C, or D. > 0.001 mg/L–10 mg/L: Method C or D. ≤ 0.001 mg/L: No testing required.

Note: ASTM—American Society for Testing and Materials, mg/L—milligrams/liters.

2. Environmental Fate and Pathways

Ready Biodegradation: Method A: ASTM E 1720–01 (Reapproved 2008) (Sealed vessel CO_2 production test) (Ref. 30).

Method B: International Organization for Standardization (ISO) 14593:1999(E) (CO_2 headspace test) (Ref. 31).

Method C: ISO 7827:1994(E) (Method by analysis of dissolved organic carbon (DOC)) (Ref. 32).

Method D: ISO 9408:1999(E) (Determination of oxygen demand in a closed respirometer) (Ref. 33).

Method E: ISO 9439:1999(E) (Carbon dioxide evolution test) (Ref. 34).

Method F: ISO 10707:1994(E) (Closed bottle test) (Ref. 35).

Method G: ISO 10708:1997(E) (Two-phase closed bottle test) (Ref. 36).

ASTM has updated its test method for Determining Ready, Ultimate, Biodegradability of Organic Chemicals in a Sealed Vessel CO_2 Production Test (ASTM E 1720–01). The test method was reapproved in 2008. There were minor changes, including the deletion of mention of specific apparatus brands in the "Apparatus" section; however the test method itself is unchanged. When required, the reapproved method (ASTM E 1720–01 (Reapproved 2008)) is listed as the required test method for the "Ready Biodegradation" endpoint in this final rule (Ref. 30).

For the "Ready Biodegradation" endpoint, EPA is requiring that the appropriate selection be made from among seven alternative methods for measuring the substance's ready biodegradability. For most test substances, EPA considers Method A (ASTM E 1720–01 (Reapproved 2008)) and Method B (ISO 14593:1999(E)) to be generally applicable, cost effective, and widely accepted internationally. However, the test method used, if any, will depend on the physical and chemical properties of the test substance, including its water solubility. An additional document, ISO 10634:1995(E) (Ref. 37), provides guidance for selection of the appropriate test method for a given test substance considering the substances physical and chemical properties. EPA is also requiring that test sponsors submit in the final study report the underlying rationale for the test standard selected for this endpoint.

3. Aquatic Toxicity

Test Group 1: Acute toxicity to fish (ASTM E 729–96 (Reapproved 2007)) (Ref. 38), Acute toxicity to Daphnia (ASTM E 729–96 (Reapproved 2007)) (Ref. 38), and Toxicity to plants (algae) (ASTM E 1218–04^{e1}) (Ref. 39).

Test Group 2: Chronic toxicity to Daphnia (ASTM E 1193–97 (Reapproved 2004)) (Ref. 40) and Toxicity to plants (algae) (ASTM E 1218–04^{e1}) (Ref. 39).

ASTM has updated its test method for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians (ASTM E 729–96 (Reapproved 2002)). The test method was reapproved in 2007. There were minor changes, for example, reference to ASTM Web site in place of *Annual Book of ASTM Standards* minor changes in references and dates, titles of ASTM documents changed to correspond to new titles, etc., however the test method itself is unchanged. When required, the updated method (ASTM E 729–96 (Reapproved 2007)) is listed as the required test method for the "Aquatic Toxicity" endpoints in this final rule (Ref. 38).

For the "Aquatic Toxicity" endpoint, the OECD HPV SIDS Program recognizes that, for certain chemical substances, acute toxicity studies are of limited value in assessing the substances' aquatic toxicity. This issue arises when considering chemical substances with high log K_{ow} values. In such cases, toxicity is unlikely to be observed over the duration of acute toxicity studies because of reduced uptake and the extended amount of time required for such substances to reach steady state or toxic concentrations in the test organism. For such situations, the OECD HPV SIDS Program recommends use of chronic toxicity testing in Daphnia in place of acute toxicity testing in fish and Daphnia. EPA is requiring that the aquatic toxicity testing requirement be determined based on the test substance's measured log K_{ow} as determined by using the approach outlined in Unit V.A.1., in the discussion of "n-Octanol/Water Coefficient," and in Table 3 in § 799.5087(j) of the regulatory text. For test substances determined to have a log K_{ow} of less than 4.2, one or more of the following tests (described as "Test Group 1" in Table 3 in § 799.5087(j) of the regulatory text) are required: Acute toxicity to fish (ASTM E 729–96 (Reapproved 2007)); Acute toxicity to Daphnia (ASTM E 729–96 (Reapproved 2007)); and Toxicity to plants (algae) (ASTM E 1218–04^{e1}). For test substances determined to have a log K_{ow} that is greater than or equal to 4.2, one or both of the following tests (described as "Test Group 2" in Table 3 in § 799.5087(j) of the regulatory text) are required: Chronic toxicity to Daphnia (ASTM E 1193–97 (Reapproved 2004)) and Toxicity to plants (algae) (ASTM E 1218–04^{e1}). As outlined in Table 3 in § 799.5087(j) of the regulatory text, depending on the testing required in Test Group 1, the Test Group 2 chronic Daphnia test may substitute for either or both the acute fish toxicity test and the acute Daphnia test.

Using SAR, a log K_{ow} of 4.2 corresponds with a fish bioconcentration factor (BCF) of about 1,000 (Refs. 29, 41, and 42). A chemical substance with a fish BCF value of 1,000 or more is characterized as having a tendency to accumulate in living organisms relative to the concentration of the chemical substance in the surrounding environment (Ref. 42). For the purposes of this final rule, EPA's use

of a log K_{ow} equal to or greater than 4.2 (which corresponds with a fish BCF value of 1,000) is consistent with the approach taken in the Agency's Final Policy Statement under TSCA section 5 (Ref. 43). EPA has also used a measured BCF that is equal to or greater than 1,000 or, in the absence of bioconcentration data, a log P [same as log K_{ow}] value equal to or greater than 4.3 to help define the potential of a new chemical substance to cause significant adverse environmental effects (Ref. 44). EPA considers the difference between the log K_{ow} of 4.3 cited in the 1989 **Federal Register** document (Ref. 44) and the log K_{ow} value of 4.2 cited in this final TSCA section 4 test rule to be negligible.

EPA recognizes that in some circumstances, acute aquatic toxicity testing (Test Group 1) may be relevant for certain chemical substances having a log K_{ow} equal to or greater than 4.2. Chemical substances that are dispersible in water (e.g., surfactants, detergents, aliphatic amines, and cationic dyes) may have log K_{ow} values greater than 4.2 and may still be acutely toxic to aquatic organisms. For any chemical substance listed in Table 3 in § 799.5087(j) of the regulatory text for which a test sponsor believes that an alternative to the log K_{ow} threshold of 4.2 is appropriate, the test sponsor may request a modification of the test standard in the final rule as described in 40 CFR 790.55. Based upon the supporting rationale provided by the test sponsor, EPA may allow an alternative threshold or method to be used for determining whether acute or chronic aquatic toxicity testing must be performed for a specific substance.

4. Mammalian Toxicity—Acute

Acute Inhalation Toxicity (rat): Method A (40 CFR 799.9130).

Acute Oral Toxicity (rat): Method B (ASTM E 1163–98 (Reapproved 2002) (Ref. 45) or 40 CFR 799.9110(d)(1)(i)(A)).

For the "Mammalian Toxicity—Acute" endpoint, EPA is requiring that certain "Special Conditions" in the form of the chemical substance's physical/chemical properties or physical state be considered in determining the appropriate test method that would be used from among those included for this endpoint in Table 3 in § 799.5087(j) of the regulatory text. The OECD HPV SIDS Program recognizes that, for most chemical substances, the oral route of administration will suffice for this endpoint. However, consistent with the approach taken under the voluntary HPV Challenge Program, EPA is requiring that, for test substances that are gases at room temperature (25 °C), the acute mammalian toxicity study be conducted using inhalation as the exposure route (described as Method A (40 CFR 799.9130) in Table 3 in § 799.5087(j) of the regulatory text). In the case of a potentially explosive test substance, care must be taken to avoid the generation of explosive concentrations. For all other chemical substances (i.e., those that are either liquids or solids at room temperature), EPA is requiring that the acute toxicity testing be conducted via oral administration using an "Up/Down" test method (described as Method B (ASTM E 1163–98 (Reapproved 2002) or 40 CFR 799.9110(d)(1)(i)(A)) in Table 3 in § 799.5087(j) of the regulatory text). Consistent with the voluntary HPV Challenge Program, EPA is allowing the use of the Neutral Red Uptake (NRU) basal cytotoxicity assay to select the starting dose for the acute oral toxicity test. This test is included as a special condition in Table 3 in § 799.5087(j) of the regulatory text. A document developed by the National Institutes of Environmental Health Sciences (NIEHS) provides guidance on how to use the NRU assay to estimate a starting dose for an acute oral toxicity test (Ref. 46). Recent versions of the standardized protocols for the NTU assay are available at the NIEHS/Interagency Coordination Committee on the Validation of Alternative Methods (ICCVAM) website (Refs. 47–49).

5. Mammalian Toxicity—Genotoxicity

Gene Mutations: Bacterial Reverse Mutation Test (*in vitro*): 40 CFR 799.9510.

Chromosomal Damage: *In Vitro* Mammalian Chromosome Aberration Test (40 CFR 799.9537), or the *In Vivo* Mammalian Bone Marrow Chromosomal Aberration Test (rodents: Mouse (preferred species), rat, or Chinese hamster) (40 CFR 799.9538), or the *In Vivo* Mammalian Erythrocyte Micronucleus Test (sampled in bone marrow) (rodents: Mouse (preferred species), rat, or Chinese hamster) (40 CFR 799.9539).

Persons required to conduct testing for chromosomal damage are encouraged to use *in vitro* genetic toxicity testing (*i.e.,* the Mammalian Chromosome Aberration Test) to generate the needed genetic toxicity screening data, unless known chemical properties preclude its use. These could include, for example, physical chemical properties or chemical class characteristics. A subject person who uses one of the *in vivo* methods instead of the *in vitro* method to address this end-point would be required to submit to EPA a rationale for conducting that alternate test in the final study report.

6. Mammalian Toxicity—Repeated Dose/Reproduction/Developmental

Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9365.

Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355.

Repeated Dose 28-Day Oral Toxicity Study: 40 CFR 799.9305.

For the "Mammalian Toxicity—Repeated Dose/Reproduction/Developmental" endpoint, EPA recommends the use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365) as the test of choice. EPA recognizes, however, that there may be reasons to test a particular chemical substance using both the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9355) and the Repeated Dose 28-Day Oral Toxicity Study (40 CFR 799.9305) instead of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365). With regard to such cases, EPA is requiring that a subject person who uses the combination of the Reproduction/Developmental Toxicity Screening Test and the Repeated Dose 28-Day Oral Toxicity Study in place of the Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screen submit to EPA a rationale for conducting these alternate tests in the final study reports.

In the proposal (Ref. 2) to this final rule, EPA stated that certain of the chemical substances for which mammalian toxicity—repeated dose/reproduction/developmental toxicity testing is required may be used solely as "closed system intermediates," and if that were the case, such chemical substances may be eligible for a reduced testing battery which substitutes a developmental toxicity study for the SIDS requirement to address repeated dose, reproduction, and developmental toxicity. EPA requested persons who believe that their chemical substance is used solely as a closed system intermediate to submit appropriate information along with their comments which substantiate this belief. If EPA agreed that the chemical substance is used solely as a closed system intermediate, EPA would defer repeated dose, reproduction, and developmental toxicity testing and address any needed developmental toxicity testing in subsequent rulemaking. In its comments on the proposal to this final rule, PETA (Ref. 50) claimed that the chemical substance phosphorochloridothioic acid, *O,O*-diethyl ester (CASRN 2524–

04–1) is a closed system intermediate; Albemarle further claimed that this chemical substance is no longer being manufactured (Ref. 51). EPA has not found, at this time, that these claims result in a change of the testing requirements for this substance. Albemarle is not the only producer of this chemical and existing production data indicate that this chemical is still an HPV chemical. Furthermore, EPA has not received any claims from a chemical manufacturer that this substance is used solely as a closed system intermediate. EPA's response to these claims is discussed in Unit E.12. of the "Response to Public Comments" document (Ref. 12).

B. When will the testing imposed by this final rule begin?

Once this final rule is effective, which is 30 days after its publication in the **Federal Register**, the required testing must be initiated at a time sufficient to allow the required final report to be submitted by the deadline indicated in § 799.5087(i) of the regulatory text.

C. How must the studies required under this test rule be conducted?

Persons required to comply with this final rule must conduct the necessary testing in accordance with the testing requirements listed in Tables 2 and 3 in § 799.5087(j) of the regulatory text, the reporting requirements described in § 799.5087(i) of the regulatory text, and with 40 CFR Part 792—TSCA Good Laboratory Practice Standards.

D. What form of test substances will be tested under this rule?

EPA is specifying two distinct approaches for identifying the specific substances that would be tested under this rule, the application of which would depend on whether the substance is considered to be a "Class 1" or a "Class 2" chemical substance. First introduced when EPA compiled the TSCA Chemical Substance Inventory, the term Class 1 chemical substance refers to a chemical substance having a chemical composition that consists of a single chemical species (not including impurities) that can be represented by a specific, complete structure diagram. By contrast, the term Class 2 chemical substance refers to a chemical substance having a composition that cannot be represented by a specific, complete chemical structure diagram, because such a substance generally contains two or more different chemical species (not including impurities). Table 2 in § 799.5087(j) of the regulatory text identifies the listed substances as either Class 1 or Class 2 substances.

The "Class 1" chemical substances listed in Table 2 in § 799.5087(j) of the regulatory text (*i.e.,* 14 of the 19 chemical substances included in this final rule) must be tested at a purity of at least 99%. In those instances in which the test sponsor(s) believes that a 99% level of purity is unattainable for a given chemical substance, the sponsor may request a modification under the procedures described in 40 CFR 790.55.

For the "Class 2" chemical substances listed in Table 2 in § 799.5087(j) of the regulatory text (*i.e.,* 5 of the 19 chemical substances included in this final rule), EPA is requiring that the substance to be tested be any representative form of the chemical substance.

In requiring a different approach for identifying the chemical substance to be tested with regard to Class 2 chemical substances, EPA recognizes two characteristics which further distinguish Class 1 from Class 2 chemical substances. First, unlike for Class 1 chemical substances, knowledge of the composition of commercial Class 2 chemical substances can vary in quality and specificity from substance to substance.

The composition of the chemical species which comprise a Class 2 chemical substance may be:

- Well-characterized in terms of molecular formulae, structural diagrams, and compositional percentages of all species present (for example, methyl phenol);
- Less well-characterized, for example, characterized only by molecular formulae, non-specific structural diagrams, and/or by incomplete or unknown compositional percentages of the species present (for example, C_{12}–C_{14} tert-alkyl amines); or
- Poorly characterized because all that is known is the identity of only some of the chemical species present and their percentages of composition, or of only the feedstocks and method of manufacture used to manufacture the substance (for example, nut shell liquor of cashew).

Secondly, the composition of some Class 2 chemical substances may vary from one manufacturer to another, or, for a single manufacturer, from production run to production run, because of small variations in feedstocks, manufacturing methods, or other production variables. A "Class 2" designation most frequently represents a group of substances that have similar combinations of different chemical species and/or that were prepared from similar feedstocks using similar production methods. By contrast, Class 1 substances generally represent a much narrower group of substances for which the only variables are their impurities. EPA believes that, for purposes of this final rule, the testing of any representative form of a subject Class 2 substance would provide the data necessary to support the development of preliminary or screening level hazard and risk characterizations for the subject Class 2 substance. However, EPA would encourage the selection of representative forms of test substances that meet industry or consensus standards, where they exist. In accordance with TSCA Good Laboratory Practice Standards (GLPS) at 40 CFR part 792, the final study report would be required to include test substance identification information, including name, CASRN, strength, purity, and composition, or other appropriate characteristics (*see* 40 CFR 792.185). In future TSCA section 4 test rules involving Class 2 substances, testing requirements relative to the number and specificity of the representative form of the substance may differ from the testing requirement in this final rule (*i.e.,* testing of any representative form of the subject Class 2 substances). For example, EPA may require testing of more than one representative form of a Class 2 chemical substance or may specify the representative form to be tested and/or may specify equivalence data that must be submitted by exemption applicants (*see* 40 CFR 790.82).

E. Am I required to test under this rule?

1. *Am I subject to this rule*? You are subject to this final rule and may be required to test if you manufacture (which is defined by statute to include import) or process, or intend to manufacture or process, one or more chemical substances listed in this final rule during the time period discussed in Unit V.E.2. However, if you do not know or cannot reasonably ascertain that you manufacture or process a chemical substance listed in this final rule (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you are not subject to this final rule for that listed substance.

2. *When will my manufacture or processing (or my intent to do so) cause me to be subject to this final rule?* You are subject to this final rule if you manufacture or process, or intend to manufacture or process, a chemical substance listed in Table 2 in § 799.5087(j) of the regulatory text at any time from the effective date of the

final test rule to the end of the test cost reimbursement period.

3. *Will I be required to test if I am subject to this final rule?* It depends on the nature of your activities. All persons who are subject to this final TSCA section 4(a) test rule, which, unless otherwise noted in the regulatory text, incorporates EPA's generic procedures applicable to TSCA section 4(a) test rules (contained within 40 CFR part 790), fall into one of two groups, designated here as Tier 1 and Tier 2. Persons in Tier 1 (those who would have to initially comply with the final rule) must either:

- Submit to EPA letters of intent to conduct testing, conduct this testing, and submit the test data to EPA, or
- Apply to and obtain from EPA exemptions from testing.

Persons in Tier 2 (those who do not have to initially comply with the final rule) need not take any action unless they are notified by EPA that they are required to do so (because, for example, no person in Tier 1 had submitted a letter of intent to conduct testing), as described in Unit V.E.3.f. Note that both persons in Tier 1 who obtain exemptions and persons in Tier 2 would nonetheless be subject to providing reimbursement to persons who actually conduct the testing, as described in Unit V.E.4.

a. *Who is in Tier 1 and Tier 2*? Table 4 of this unit describes who is in Tier 1 and Tier 2.

TABLE 4—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2

Tier 1 (Persons initially required to comply)	Tier 2 (Persons not initially required to comply)
Persons who manufacture (as defined at TSCA section 3(7)), or intend to manufacture, a test rule substance, and who are not listed under Tier 2.	A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a test rule substance solely as one or more of the following: —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring chemical substance (as defined at 40 CFR 710.4(b)); —As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kg (1,100 lbs) annually (as described at 40 CFR 790.42(a)(4)); or —In small quantities solely for R&D (as described at 40 CFR 790.42(a)(5)). B. Persons who process (as defined at TSCA section 3(10)) or intend to process a test rule substance (see 40 CFR 790.42(a)(2)).

Note: kg—kilogram, R&D—research and development, TSCA—Toxic Substances Control Act.

Under 40 CFR 790.2, EPA may establish procedures applying to specific test rules that differ from the generic procedures governing TSCA section 4(a) test rules in 40 CFR part 790. For purposes of this final rule, EPA has established certain requirements that differ from those under 40 CFR part 790.

In this final test rule, EPA has reconfigured the tiers in 40 CFR 790.42. In addition to processors, manufacturers of less than 500 kilograms (kgs) (1,100 lbs) per year (small-volume manufacturers), and manufacturers of small quantities for research and development (R&D manufacturers), EPA has added the following persons to Tier 2:

Byproduct manufacturers, impurity manufacturers, manufacturers of naturally occurring substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 substances. The Agency took administrative burden and complexity into account in determining who was to be in Tier 1 in this final rule. EPA believes that those persons in Tier 1 who are required to conduct testing under this final rule are generally large chemical manufacturers who, in the experience of the Agency, have traditionally conducted testing or participated in testing consortia under previous TSCA section 4(a) test rules.

The Agency also believes that byproduct manufacturers, impurity manufacturers, manufacturers of naturally occurring substances, manufacturers of non-isolated intermediates, and manufacturers of components of Class 2 substances historically have not themselves participated in testing or contributed to reimbursement of those persons who have conducted testing. EPA understands that these manufacturers may include persons for whom the marginal transaction costs involved in negotiating and administering testing arrangements are deemed likely to raise the expense and burden of testing to a level that is disproportional to the additional benefits of including these persons in Tier 1. Therefore, EPA does not believe that the likelihood of the persons added to Tier 2 actually conducting the testing is sufficiently high to justify burdening these persons with Tier 1 requirements (*e.g.,* submitting requests for exemptions). Nevertheless, these persons, along with all other persons in Tier 2, would be subject to reimbursement obligations to persons who actually conduct the testing, as described in Unit V.E.4.

TSCA section 4(b)(3)(B) requires all manufacturers and/or processors of a chemical substance to test that chemical substance if EPA has made findings under TSCA section 4(a)(1)(A)(ii) or TSCA section 4(a)(1)(B)(ii) for that chemical substance, and issued a TSCA section 4(a) test rule requiring testing. However, practicality must be a factor in determining who is subject to a particular test rule. Thus, persons who do not know or cannot reasonably ascertain that they are manufacturing or processing a substance subject to this final rule, (*e.g.,* manufacturers or processors of a substance as a trace contaminant who are not aware of and cannot reasonably ascertain these activities) are not be subject to the rule. See Unit V.E.1. and § 799.5087(b)(2) of the regulatory text.

b. *Subdivision of Tier 2 entities.* In this final rule the Agency has prioritized which persons in Tier 2 would be required to perform testing, if needed. Specifically, the Agency subdivided Tier 2 entities into:

i. *Tier 2A.* Tier 2 manufacturers, *i.e.,* those who manufacture, or intend to manufacture, a test rule chemical substance solely as one or more of the

following: A byproduct, an impurity, a naturally occurring substance, a non-isolated intermediate, a component of a Class 2 chemical substance, in amounts less than 1,100 lbs annually, or in small quantities solely for research and development.

ii. *Tier 2B.* Tier 2 processors, *i.e.* those who process, or intend to process, a test rule chemical substance (in any form). The terms "process" and "processor" are defined by TSCA section 3(10) and TSCA section 3(11), respectively.

If the Agency needs testing from persons in Tier 2, EPA would seek testing from persons in Tier 2A before proceeding to Tier 2B. It is appropriate to require manufacturers in Tier 2A to submit letters of intent to test or exemption applications before processors are called upon because the Agency believes that testing costs are traditionally passed by manufacturers along to processors, enabling them to share in the costs of testing (Ref. 52). In addition, "[t]here are [typically] so many processors [of a given test rule chemical substance] that it would be difficult to include them all in the technical decisions about the tests and in the financial decisions about how to allocate the costs" (Ref. 53).

c. *When is it appropriate for a person required to comply with the rule to apply for an exemption rather than to submit a letter of intent to conduct testing?* You may apply for an exemption if you believe that the required testing will be performed by another person (or a consortium of persons formed under TSCA section 4(b)(3)(A)). You can find procedures relating to exemptions in 40 CFR 790.80 through 790.99, and § 799.5087(c)(2), (c)(5), (c)(7), and (c)(11) of the regulatory text. In this final rule, EPA will not require the submission of equivalence data (i.e., data demonstrating that your substance is equivalent to the substance actually being tested) as a condition for approval of your exemption. Therefore, 40 CFR 790.82(e)(1) and 790.85 do not apply to this final rule.

d. *What will happen if I submit an exemption application?* EPA believes that requiring the collection of duplicative data is unnecessarily burdensome. As a result, if EPA has received a letter of intent to test from another source or has received (or expects to receive) the test data that would be required under this rule, the Agency would conditionally approve your exemption application under 40 CFR 790.87.

The Agency would terminate conditional exemptions if a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA. EPA may then require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5087(c)(8) of the regulatory text. In addition, the Agency would terminate a conditional exemption if no letter of intent to test has been received by persons required to comply with the rule. See, e.g., § 799.5087(c)(6) of the regulatory text. Note that the provisions at 40 CFR 790.48(b) have been incorporated into the regulatory text of this final rule; thus, persons subject to this final rule are not required to comply with 40 CFR 790.48 itself (see § 799.5087(c)(4)–(c)(7) and § 799.5087(d)(3) of the regulatory text). Note that persons who obtain exemptions or receive them automatically would nonetheless be subject to providing reimbursement to persons who do actually conduct the testing, as described in Unit V.E.4.

e. *What are my obligations if I am in Tier 2?* If you are in Tier 2, you would be subject to the rule and you would be responsible for providing reimbursement to persons in Tier 1, as described in Unit V.E.4. You are considered to have an automatic conditional exemption. You do not need to submit a letter of intent to test or an exemption application unless you are notified by EPA that you are required to do so.

If a problem occurs with the initiation, conduct, or completion of the required testing, or with the submission of the required data to EPA, the Agency may require you to submit a notice of intent to test or an exemption application. See 40 CFR 790.93 and § 799.5087(c)(10) of the regulatory text.

In addition, you will need to submit a notice of intent to test or an exemption application if:

- No manufacturer in Tier 1 has notified EPA of its intent to conduct testing; and
- EPA has published a **Federal Register** document directing persons in Tier 2 to submit to EPA letters of intent to conduct testing or exemption applications.

See § 799.5087(c)(4), (c)(5), (c)(6), and (c)(7) of the regulatory text. The Agency will conditionally approve an exemption application under 40 CFR 790.87, if EPA has received a letter of intent to test or has received (or expects to receive) the test data required under this rule. EPA is not aware of any circumstances in which test rule Tier 1 entities have sought reimbursement from Tier 2 entities either through private agreements or by soliciting the involvement of the Agency under the reimbursement regulations at 40 CFR part 791.

f. *What will happen if no one submits a letter of intent to conduct testing?* EPA anticipates that it will receive letters of intent to conduct testing for all of the tests specified and chemical substances included in this final rule. However, in the event it does not receive a letter of intent for one or more of the tests required for any of the chemical substances in this rule within 30 days after the publication of a **Federal Register** document notifying Tier 2 manufacturers and processors of the obligation to submit a letter of intent to conduct testing or to apply for an exemption from testing, EPA will notify all manufacturers and processors of the chemical substance of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document will additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and will give them an opportunity to take corrective action. If no one has notified EPA of its intent to conduct the required testing of the chemical substance within 30 days after receipt of the certified letter or publication of the **Federal Register** document, all manufacturers and processors subject to the rule with respect to that chemical substance who are not already in violation of the rule would be in violation of the rule.

4. *How do the reimbursement procedures work?* In the past, persons subject to test rules have independently worked out among themselves their respective financial contributions to those persons who have actually conducted the testing. However, if persons are unable to agree privately on reimbursement, they may take advantage of EPA's reimbursement procedures at 40 CFR part 791, promulgated under the authority of TSCA section 4(c). These procedures include: The opportunity for a hearing with the American Arbitration Association; publication by EPA of a document in the **Federal Register** concerning the request for a hearing; and the appointment of a hearing officer to propose an order for fair and equitable reimbursement. The hearing officer may base his or her proposed order on the production volume formula set out at 40 CFR 791.48, but is not obligated to do so. Under this final rule, amounts manufactured as impurities would be included in production volume (40 CFR 791.48(b)), subject to the discretion of the hearing officer (40

CFR 791.40(a)). The hearing officer's proposed order may become the Agency's final order, which is reviewable in Federal court (40 CFR 791.60).

F. What are the reporting requirements under this final rule?

A final report must be submitted for each test for each chemical substance 13 months after the effective date of the final rule, i.e., by the deadline indicated in § 799.5087(i) of the regulatory text. EPA also requests that a robust summary of the final report for each specific test be submitted in addition to and at the same time as the final report. The term "robust summary" is used to describe the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report which can be either an experiment or in some cases an estimation or prediction method. Guidance for the compilation of robust summaries is described in a document entitled "Draft Guidance on Developing Robust Summaries" (Ref. 19). Persons who submit robust summaries are also encouraged to submit the robust summary electronically via HPVIS to allow for its ready incorporation into HPVIS. Directions for electronic submission of robust summary information into HPVIS are provided at *https://iaspub.epa.gov/oppthpv/metadata.html.* This link will direct you to the "HPVIS Quick Start and User's Guide."

G. What would I need to do if I cannot complete the testing required by the final rule?

A company that submits a letter of intent to test under the final rule and that subsequently anticipates difficulties in completing the testing by the deadline set forth in the final rule may submit a modification request to the Agency, pursuant to 40 CFR 790.55. EPA will determine whether modification of the test schedule is appropriate, and may first seek public comment on the modification.

H. Will there be sufficient test facilities and personnel to undertake the testing required under this test rule?

EPA's most recent analysis of laboratory capacity (Ref. 54) indicates that available test facilities and personnel would adequately accommodate the testing specified in this rule.

I. Might EPA seek further testing of the chemical substances in this final test rule?

If EPA determines that it needs additional data regarding any of the chemical substances included in this final rule, the Agency would seek further health and/or environmental effects testing for these chemical substances. Should the Agency decide to seek such additional testing via a test rule, EPA would initiate a separate action for this purpose.

VI. Export Notification

Any person who exports, or intends to export, one of the chemical substances contained in this final rule in any form (*e.g.,* as byproducts, impurities, components of Class 2 substances, etc.) is subject to the export notification requirements in TSCA section 12(b)(1) and 40 CFR part 707, subpart D. Export notification is generally not required for articles, as provided by 40 CFR 707.60(b). Section 12(b) of TSCA states, in part, that any person who exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under TSCA section 4 must notify the EPA Administrator of such export or intent to export. The EPA Administrator in turn will notify the government of the importing country of EPA's regulatory action with respect to the substance.

VII. Decision Not To Require Testing for Certain Endpoints

For certain testing endpoints for certain chemicals listed in the proposed rule, EPA is not making the TSCA section 4(a)(1)(B)(ii) finding that "* * * there are insufficient data and experience to reasonably determine or predict the effects of the manufacture, processing, or use of these chemical substances, or of any combination of such activities, on human health or the environment * * *" and is not finalizing the proposed testing. Table 2 in § 799.5087(j) of the regulatory text, which lists the chemical substances and testing requirements, has been revised to reflect this. Further discussion follows in Units VII.A. through VII.F.

A. Screening Reproduction/Developmental Toxicity of 2,4-Hexadienoic Acid, (E,E)-

As discussed in Unit E.3. of the "Response to Public Comments" document (Ref. 12), EPA reviewed additional data, including studies submitted by the PETA (PETA submitted on behalf of themselves and other Animal Welfare Organizations (AWOs)) for 2,4-hexadienoic acid, (*E,E*)-(CASRN 110–44–1), also known as sorbic acid. After reviewing these data, EPA finds existing studies are adequate to evaluate reproduction/developmental toxicity and is not finalizing the proposed testing for reproduction/developmental toxicity for sorbic acid.

B. Screening Reproduction/Developmental Toxicity of Ethanedioic Acid

As discussed in Unit E.4. of the "Response to Public Comments" document (Ref. 12), EPA reviewed additional data, including studies submitted by PETA (PETA submitted on behalf of themselves and other AWOs) for ethanedioic acid (CASRN 144–62–7). After reviewing these data, EPA finds existing studies are adequate to evaluate reproduction/developmental toxicity and is not finalizing the proposed testing for reproduction/developmental toxicity for ethanedioic acid. However, as further discussed in the "Response to Public Comments" document, EPA finds studies submitted for other endpoints inadequate and is still requiring the testing of ethanedioic acid for chromosomal damage, aquatic toxicity and chemical/physical endpoints as described in Table 2 in § 799.5087(j) of the regulatory text.

C. Physical Chemical Properties and Aquatic Toxicity of Castor Oil, Oxidized, and Physical Chemical Properties of Castor Oil, Sulfated, Sodium Salt

As discussed in Unit E.7. of the "Response to Public Comments" document (Ref. 12), EPA reviewed data submitted by Vertellus on vapor pressure, water solubility, and Log K_{ow}. Based on information provided by Vertellus, indicating the extremely low water solubility and vapor pressure, and extremely high Log K_{ow} of this substance, EPA is not finalizing the proposed testing for these endpoints for castor oil, oxidized (CASRN 68187–84–8). In addition, EPA agrees with Vertellus that the extreme insolubility of this substance makes aquatic toxicity testing for this chemical substance not feasible. Therefore, EPA is not finalizing the proposed testing for aquatic toxicity testing for castor oil, oxidized. However, EPA is still requiring a "melting point" test be conducted for this substance. EPA acknowledges Vertellus' comment that the substance is a liquid at room temperature. In these cases the melting point determination would actually involve determination of a freezing point. Since ASTM E 324–99 (capillary tube) does not specifically include instructions for determining a freezing point, for that particular endpoint EPA

is requiring OECD Guideline 102 (melting point/melting range) be used instead of ASTM E 324–99 for that test. Furthermore, as discussed in Unit E.7. of the "Response to Public Comments" document, because of its structural similarity with castor oil, oxidized, EPA is also not requiring water solubility and log K_{ow} for castor oil, sulfated, sodium salt (CASRN 68187–76–8). However, because of its surfactant properties, EPA is still requiring aquatic toxicity testing for castor oil, sulfated, sodium salt.

D. Mammalian Toxicity—Acute, of Castor Oil, Oxidized

As discussed in Unit E.7. of the "Response to Public Comments" document (Ref. 12), EPA reviewed data submitted by Vertellus on acute toxicity of oxidized castor oil (CASRN 68187–84–8) and has concluded that these data are adequate. However, while EPA believes that data for certain endpoints, as just discussed, are adequate for castor oil, sulfated; and castor oil, oxidized; data are still needed on the other endpoints listed for these chemical substances in Table 2 in § 799.5087(j) of the regulatory text, including, for castor oil, sulfated, mammalian acute toxicity testing, for which EPA received no data contraindicating this testing need.

E. Boiling Point of Benzenediamine, Ar,Ar-Diethyl-Ar-Methyl-

Boiling point is not required for benzenediamine, ar,ar-diethyl-ar-methyl- (CASRN 68479–98–1), as discussed in Unit E.8. of the "Response to Public Comments" document (Ref. 12). Albemarle provided EPA with data which are adequate for this endpoint.

F. Acute Mammalian Toxicity, Repeated-Dose Toxicity, and Mutagenicity Endpoints of Alkenes, $C_{12–24}$, Chloro

As discussed in Unit E.9. of the "Response to Public Comments" document (Ref. 12), EPA reviewed additional data including studies submitted by AWOs and CPIA. In addition to data on this group of chemicals, comments focused on the potential acceptability of using analog data available for other similar classes of chlorinated paraffins. For certain proposed tests, EPA has accepted certain of these data, including analog data on similar substances. However, for other testing endpoints, EPA does not agree that the surrogate chemicals are acceptable analogs, or has found some of the submitted studies inadequate. Specifically, EPA finds that data are acceptable for the acute mammalian, repeated-dose, and mutagenicity endpoints. EPA continues to require testing on physical/chemical properties (all), biodegradation, aquatic toxicity testing (C1, Test Group 2), *in vitro* chromosomal aberrations, and reproductive and developmental toxicity.

VIII. Economic Impacts

EPA has prepared an economic assessment entitled "Economic Impact Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals" (Ref. 55), a copy of which has been placed in the docket this final rule. This economic assessment evaluates the potential for significant economic impacts as a result of the testing required by this final rule. The analysis covers 19 chemical substances. The total social cost of providing test data on the 19 chemical substances that were evaluated in this economic analysis is estimated to be $4.19 million. (Ref. 55).

While legally subject to this test rule, processors of a subject chemical substance would be required to comply with the requirements of the rule only if they are directed to do so by EPA as described in § 799.5087(c)(5) and (c)(6) of the regulatory text. EPA would only require processors to test if no person in Tier 1 has submitted a notice of its intent to conduct testing, or if under 40 CFR 790.93, a problem occurs with the initiation, conduct, or completion of the required testing or the submission of the required data to EPA. Because EPA has identified at least one manufacturer in Tier 1 for each subject chemical substance, the Agency assumes that, for each chemical substance in this final rule, at least one such person will submit a letter of intent to conduct the required testing and that person will conduct such testing and will submit the test data to EPA. Because EPA does not expect that processors will need to comply with the final rule, the economic assessment does not address processors.

To evaluate the potential for an adverse economic impact of testing on manufacturers of the chemical substances in this final rule, EPA employed a screening approach that estimated the impact of testing requirements as a percentage of each chemical substance's sale price. This measure compares annual revenues from the sale of a chemical substance to the annualized compliance cost for that chemical substance to assess the percentage of testing costs that can be accommodated by the revenue stream generated by that chemical substance over a number of years. Compliance costs include costs of testing and administering the testing, as well as reporting costs. Annualized compliance costs divide testing expenditures into an equivalent, constant yearly expenditure over a longer period of time. To calculate the percent price impact, testing costs (including laboratory and administrative expenditures) are annualized over 15 years using a 7% discount rate. Annualized testing costs are then divided by the estimated annual revenue of the chemical substance to derive the cost-to-sales ratio. EPA estimates the total annualized compliance cost of testing for the 19 chemical substances evaluated in the economic analysis to be $1.48 million under the average cost scenario. In addition, the TSCA section 12(b) export notification requirements (included in the total and annualized cost estimates) that would be triggered by this final rule are expected to have a negligible impact on exporters. The estimated cost of the TSCA section 12(b) export notification requirements, which, under this final rule, would be required for the first export to a particular country of a chemical substance subject to the rule, is estimated to range from $25.56 per notice to $80.22 per notice (Ref. 55). The Agency's estimated total costs of testing (including both laboratory and administrative costs) annualized testing cost, and public reporting burden hours for this final rule are presented in the economic assessment.

Under a least cost scenario, 16 out of the 19 chemical substances (84%) would have a price impact at less than the 1% level. Similarly, 15 out of the 19 chemical substances (79%) would be impacted at less than the 1% level under an average cost scenario. Thus, the potential for adverse economic impact due to this final test rule is low for at least 79% of the chemical substances in this rule. Approximately 4 chemical substances (21%) of the 19 chemical substances for which price data are available would have a price impact at a level greater than or equal to 1% under the least (average) cost scenario.

EPA believes, on the basis of these calculations, that the testing of the chemical substances in this final rule presents a low potential for adverse economic impact for the majority of chemical substances. Because the subject chemical substances have relatively large production volumes, the annualized costs of testing, expressed as a percentage of annual revenue, are very small for most chemical substances. There are, however, some chemical substances for which the price impact is expected to exceed 1% of the revenue from that chemical substance. The potential for adverse economic impact is

expected to be higher for these chemical substances. In these cases, companies may choose to use revenue sources other than the profits from the individual chemical substances to pay for testing. Smaller businesses are less likely to have additional revenue sources to cover the compliance costs in this situation. Therefore, the Agency also compared the costs of compliance to company sales for small businesses.

EPA does not provide quantitative estimates of the benefits from these tests. Ideally, a discussion of benefits would focus on the additional benefits to be gained from new information relative to information that already exists. Such an approach could examine the value of new information provided as a result of the test rule where such information has not been publicly available. Because of constraints on information on the value of information, our evaluation of benefits is qualitative and does not address incremental benefits. We believe, however, that the net benefits of the new information are positive.

X. Materials in the Docket

As indicated under **ADDRESSES**, a docket was established for this final rule under docket ID number EPA–HQ–OPPT–2007–0531. The following is a listing of the documents that have been placed in the docket for this final rule. The docket includes information considered by EPA in developing this final rule, including the documents listed in this unit, which are physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that EPA has placed in the docket, regardless of whether these referenced documents are physically located in the docket. For assistance in locating documents that are referenced in documents that EPA has placed in the docket, but that are not physically located in the docket, consult either of the technical persons listed under **FOR FURTHER INFORMATION CONTACT**. The docket is available for review as specified under **ADDRESSES**.

1. EPA. Data Collection and Development on High Production Volume (HPV) Chemicals. Notice. **Federal Register** (65 FR 81686, December 26, 2000) (FRL–6754–6).

2. EPA. Testing of Certain High Production Volume Chemicals; Second Group of Chemicals. Proposed Rule. **Federal Register** (73 FR 43314, July 24, 2008) (FRL–8373–9).

3. EPA. Testing of Certain High Production Volume Chemicals. Proposed Rule. **Federal Register** (65 FR 81658, December 26, 2000) (FRL–6758–4).

4. EPA. Testing of Certain High Production Volume Chemicals. Final Rule. **Federal Register** (71 FR 13707, March 16, 2006) (FRL–7335–2).

5. EPA. Testing of Certain High Production Volume Chemicals; Third Group of Chemicals. Proposed Rule. **Federal Register** (75 FR 8575, February 25, 2010) (FRL–8805–8).

6. EPA. TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, Substantial or Significant Human Exposure. Notice. **Federal Register** (58 FR 28736, May 14, 1993).

7. EPA, Office of Pollution Prevention and Toxics (OPPT). HPV Challenge Program Chemical List. Available on-line at: *http://www.epa.gov/oppt/chemrtk/pubs/update/hpvchmlt.htm.*

8. OECD Secretariat. Manual for the Investigation of HPV Chemicals. OECD Programme on the Co-Operative Investigation of High Production Volume Chemicals. Paris, France. September 2004. Available on-line at: *http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.htm.*

9. ICCA. ICCA HPV Working List of Chemicals. October 2005. Available on-line at: *http://www.cefic.org/activities/hse/mgt/hpv/hpvinit.htm* and *http://www.iccahpv.com/hpvchallenge/about.cfm.*

10. EPA. TSCA Section 4(a)(1)(B) Proposed Statement of Policy. Notice. **Federal Register** (56 FR 32294, July 15, 1991).

11. Chemical Manufacturing Association (CMA) now American Chemistry Council (ACC). Comments on EPA's TSCA section 4(a)(1)(B) Proposed Statement of Policy submitted to the TSCA Public Docket Office, EPA. September 13, 1991.

12. EPA, OPPT, Chemical Information and Testing Branch (CITB). Response to public comments regarding testing of certain high production volume chemicals. August 2010.

13. EPA, OPPT, Economics, Exposure and Technology Division (EETD). Testing of Certain High Production Volume Chemicals-2 (Exposure Findings Supporting Information). July 2010.

14. Department of Health and Human Services (DHHS), Centers for Disease Control (CDC), NIOSH. National occupational exposure survey field guidelines. Vol. I. Seta, J.A.; Sundin, D.S.; and Pedersen, D.H., eds. Cincinnati, OH. DHHS (NIOSH) Publication No. 88–106. Available on-line at: *http://www.cdc.gov/niosh/88-106.html.* 1988.

15. DHHS, CDC, NIOSH. National occupational exposure survey analysis of management interview responses. Vol. III. Pedersen, D.H. and Sieber, W.K., eds. Cincinnati, OH. DHHS (NIOSH) Publication No. 89–103. Available on-line at: *http://www.cdc.gov/niosh/89-103.html.* 1989.

16. DHHS, CDC, NIOSH. National occupational exposure survey sampling methodology. Vol. II. Sieber, W.K., ed. Cincinnati, OH. DHHS (NIOSH) Publication No. 89–102. Available on-line at: *http://www.cdc.gov/niosh/89–102.html.* 1989.

17. EPA. TSCA Inventory Update Rule Amendments. Final Rule. **Federal Register** (68 FR 848, January 7, 2003) (FRL–6767–4).

18. EPA. TSCA Inventory Update Reporting Revisions. Final Rule. **Federal Register** (70 FR 75059, December 19, 2005) (FRL–7743–9).

19. EPA, OPPT. Draft Guidance on Developing Robust Summaries. October 22, 1999. Available on-line at: *http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm.*

20. EPA. OPPT. High Production Volume Chemical Data Information System (HPVIS). Data from HVPIS on eighteen HPV chemicals. May 2008.

21. ASTM International. Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals. ASTM E 324–99. 1999.

22. ASTM International. Standard Test Method for Vapor Pressure of Liquids by Ebulliometry. ASTM E 1719–05. 2005.

23. ASTM International. Standard Test Method for Determining Vapor Pressure by Thermal Analysis. ASTM E 1782–08. 2008.

24. ASTM International. Standard Test Method for Partition Coefficient (*n*-Octanol/Water) Estimation by Liquid Chromatography. ASTM E 1147–92 (Reapproved 2005).

25. OECD. Guideline for the Testing of Chemicals: Melting Point/Melting Range. OECD 102. July 27, 1995.

26. ASTM International. Standard Test Method for Measurements of Aqueous Solubility. ASTM E 1148–02 (Reapproved 2008).

27. ASTM International. Question about ASTM E 324. E-mail from Diane Rehiel, ASTM, to Greg Schweer, CITB, Chemical Control Division, OPPT, EPA. September 15, 2004.

28. Meylan, W.M. and Howard, P.H. Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients. *Journal of Pharmaceutical Sciences.* 84(1):83–92. 1995.

29. Meylan, W.M.; Howard, P.H.; and Boethling, R.S. Improved Method for Estimating Water Solubility from Octanol/Water Partition Coefficient. *Environmental Toxicology and Chemistry.* 15(2):100–106. 1996.

30. ASTM International. Standard Test Method for Determining Ready, Ultimate, Biodegradability of Organic Chemicals in a Sealed Vessel CO_2 Production Test. ASTM E 1720–01 (Reapproved 2008).

31. International Organization for Standardization (ISO). Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Method by Analysis of Inorganic Carbon in Sealed Vessels (CO_2 Headspace Test). ISO 14593:1999(E).

32. ISO. Water Quality—Evaluation in an Aqueous Medium of the "Ultimate" Aerobic Biodegradability of Organic Compounds—Method by Analysis of Dissolved Organic Carbon (DOC). ISO 7827:1994(E).

33. ISO. Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium By Determination Of Oxygen Demand in a Closed Respirometer. ISO 9408:1999(E).

34. ISO. Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Carbon Dioxide Evolution Test. ISO 9439:1999(E).

35. ISO. Water Quality—Evaluation in an Aqueous Medium of the "Ultimate" Aerobic Biodegradability of Organic Compounds—Method by Analysis of Biochemical Oxygen Demand (Closed Bottle Test). ISO 10707:1994(E).

36. ISO. Water Quality—Evaluation in an Aqueous Medium of the Ultimate Aerobic Biodegradability of Organic Compounds—Determination Of Biochemical Oxygen Demand in a Two-Phase Closed Bottle Test (available in English only). ISO 10708:1997(E).

37. ISO. Water Quality—Guidance for the Preparation and Treatment of Poorly Water-Soluble Organic Compounds for the Subsequent Evaluation of Their Biodegradability in an Aqueous Medium. ISO 10634:1995(E).

38. ASTM International. Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians. ASTM E 729–96 (Reapproved 2007).

39. ASTM International. Standard Guide for Conducting Static Toxicity Tests with Microalgae. ASTM E 1218–04^{e1}. 2004.

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X. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this rule is not a "significant regulatory action" subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, because it does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in section 3(f)(4) of the Executive Order. Accordingly, EPA did not submit this final rule to OMB for review under Executive Order 12866.

EPA has prepared an economic analysis of this action, which is contained in a document entitled *Economic Impact Analysis for the Final Section 4 Test Rule for High Production Volume Chemicals–2* (Ref. 55). A copy of the economic analysis is available in the docket for this final rule and is summarized in Unit VIII.

B. Paperwork Reduction Act

This final rule does not impose any new or amended paperwork collection requirements that would require additional review and/or approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements contained in TSCA section 4 test rules have already been approved by OMB under PRA, and have been assigned OMB control number 2070–0033 (EPA ICR No. 1139). In the context of developing a new test rule, the Agency must determine whether the total annual burden covered by the approved ICR needs to be amended to accommodate the burden associated with the new test rule. If so the Agency must submit an Information Correction Worksheet (ICW) to OMB and obtain OMB approval of an increase in the total approved annual burden in the approved EPA ICR No. 0795. The Agency's estimated burden for this test rule is provided in the economic analysis (Ref. 55).

The information collection activities related to export notification under TSCA section 12(b)(1) are already approved under OMB control number 2070–0030 (EPA ICR No. 0795). This final rule does not impose any new or changes to the export notification requirements, and is not expected to result in any substantive changes in the burden estimates for EPA ICR No. 0795 that would require additional review and/or approval by OMB. Under PRA, an agency may not conduct or sponsor, and a person is not required to respond to, an information collection request unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and included on the related collection instrument. EPA is amending the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This ICR was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. In addition, EPA is correcting typographical errors in several listings which were introduced into the table by a final rule published in the **Federal Register** issue of June 30, 2010 (75 FR 37722) (FRL–8833–7).

As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), to amend this table without further notice and comment.

The standard chemical testing program involves the submission of letters of intent to test (or exemption applications), study plans, semi-annual progress reports, test results, and some administrative costs. For this final rule, EPA estimates the public reporting burden for all 19 chemical substances is 9,008 hours, with an estimated burden per chemical substance of 474 hours (Ref. 55). The estimated burden of the information collection activities related to export notification is estimated to average 1 burden hour for each chemical substance/country combination for an initial notification and 0.5 hours for each subsequent notification (Ref. 55). In estimating the total burden hours approved for the information collection activities related to export notification, the Agency has included sufficient burden hours to accommodate any export notifications that may be required by the Agency's issuance of final test rules for chemical substances. As such, EPA does not expect to need to request an increase in the total burden hours approved by OMB for export notifications.

As defined by PRA and 5 CFR 1320.3(b), "burden" means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to: Review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* after considering the potential economic impacts on small entities, the Agency hereby certifies that this final rule would not have a significant adverse economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the economic analysis for this final rule (Ref. 55), which is summarized in Unit VIII., and a copy of which is available in the docket for this final rule. The following is a brief summary of the factual basis for this certification.

Under RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this final rule on small entities, small entity is defined in accordance with RFA as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201.

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. Based on the industry profile that EPA prepared as part of the economic analysis for this final rule (Ref. 55), EPA has determined that this final rule is not expected to impact any small not-for-profit organizations or small governmental jurisdictions. As such, the Agency's analysis presents only the estimated potential impacts on small business.

Two factors are examined in EPA's small entity impact analysis (Ref. 55) in order to characterize the potential small entity impacts of this final rule on small business:

- The size of the adverse economic impact (measured as the ratio of the cost to sales or revenue).
- The total number of small entities that experience the adverse economic impact. Section 601(3) of RFA establishes as the default definition of "small business" the definition used in section 3 of the Small Business Act, 15 U.S.C. 632, under which SBA establishes small business size standards (13 CFR 121.201). For this final rule, EPA has analyzed the potential small business impacts using the size standards established under this default definition. The SBA size standards, which are primarily intended to determine whether a business entity is eligible for government programs and preferences reserved for small businesses (13 CFR 121.101), "seek to ensure that a concern that meets a specific size standard is not dominant in its field of operation." (13 CFR 121.102(b)). See section 632(a)(1) of the Small Business Act. In analyzing potential impacts, RFA recognizes that it may be appropriate at times to use an alternate definition of small business. As such, section 601(3) of RFA provides that an agency may establish a different

definition of small business after consultation with the SBA Office of Advocacy and after notice and an opportunity for public comment. Even though the Agency has used the default SBA definition of small business to conduct its analysis of potential small business impacts for this final rule, EPA does not believe that the SBA size standards are generally the best size standards to use in assessing potential small entity impacts with regard to TSCA section 4(a) test rules.

The SBA size standard is generally based on the number of employees an entity in a particular industrial sector may have. For example, in the chemical manufacturing industrial sector (i.e., NAICS code 325 and NAICS code 324110), approximately 98% of the firms would be classified as small businesses under the default SBA definition. The SBA size standard for 75% of this industry sector is 500 employees, and the size standard for 23% of this industry sector is either 750; 1,000; or 1,500 employees. When assessing the potential impacts of test rules on chemical manufacturers, EPA believes that a standard based on total annual sales may provide a more appropriate means to judge the ability of a chemical manufacturing firm to support chemical testing without significant costs or burdens.

EPA is currently determining what level of annual sales would provide the most appropriate size cutoff with regard to various segments of the chemical industry usually impacted by TSCA section 4(a) test rules, but has not yet reached a determination. As stated above, therefore, the factual basis for the RFA determination for this final rule is based on an analysis using the default SBA size standards. Although EPA is not currently proposing to establish an alternate definition for use in the analysis conducted for this final rule, the analysis for this final rule also presents the results of calculations using a standard based on total annual sales (40 CFR 704.3).

The SBA has developed 6-digit NAICS code-specific size standards based on employment thresholds. These size standards range from 500 to 1,500 employees for the various 6-digit NAICS codes that are potentially impacted (Ref. 55). For a conservative estimate of the number of small businesses affected by the HPV rule, the Agency chose an employment threshold of less than 1,500 employees for all businesses regardless of the NAIC-specific threshold to determine small business status.

For each manufacturer of the 19 chemical substances covered by this final rule, the parent company (ultimate corporate entity (UCE)) was identified and sales and employment data were obtained for companies where data was publicly available. The search determined that there were 48 affected UCEs. Sales and employment data could be found for 45 and 46 of these UCEs (88%), respectively.

Parent company sales data were collected to identify companies that qualified as a "small business" for purposes of RFA analysis. Based on the SBA size standard applied (1,500 employees or less), 20 companies were identified as small.

The potential significance of this final rule's impact on small businesses was analyzed by examining the number of small entities that experienced different levels of costs as a percentage of their sales. Small businesses were placed in the following categories on the basis of cost-to-sales ratios: Less than 1%, greater than 1%, and greater than 3%. This analysis was conducted under both a least- and average-cost scenario.

Of the 20 small businesses analyzed for small business impacts, one company had no sales data available. Another two companies could not be classified as small or large because there were no employment data available, but were still included in the small business impact analysis. Of the 19 designated as small businesses, none had cost-to-sales ratios of greater than 1% under both the least- and average-cost scenarios. For the chemical substances where sales data were unavailable, EPA used the median sales value sales of all other small businesses equal to $15.4 million. The costs for the three companies were estimated to be well below 0.01% of this sales level. Given these results, the Agency has determined that there is not a significant economic impact on a substantial number of small entities as a result of this final rule.

The estimated cost of the TSCA section 12(b)(1) export notification, which, as a result of the final rule, would be required for the first export to a particular country of a chemical substance subject to the rule, is estimated to be $80.22 for the first time that an exporter must comply with TSCA section 12(b)(1) export notification requirements, and $25.56 for each subsequent export notification submitted by that exporter (Refs. 55–57). EPA has concluded that the costs of TSCA section 12(b)(1) export notification would have a negligible impact on exporters of the chemical substances in the final rule, regardless of the size of the exporter.

D. Unfunded Mandates Reform Act

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. It is estimated that the total aggregate costs of this final rule, which are summarized in Unit VIII., would be $4.19 million. The total annualized costs of this final rule are estimated to be $1.48 million. In addition, since EPA does not have any information to indicate that any State, local, or tribal government manufactures or processes the chemical substances covered by this action such that this rule would apply directly to State, local, or tribal governments, EPA has determined that this final rule would not significantly or uniquely affect small governments. Accordingly, this final rule is not subject to the requirements of sections 202, 203, 204, and 205 of UMRA.

E. Executive Order 13132

Under Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this final rule does not have "federalism implications" because it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in the Executive Order. This final rule would establish testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemical substances. Because EPA has no information to indicate that any State or local government manufactures or processes the chemical substances covered by this action, this rule does not apply directly to States and localities and will not affect State and local governments. Thus, Executive Order 13132 does not apply to this final rule.

F. Executive Order 13175

Under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), EPA has determined that this final rule does not have tribal implications because it will not have any affect on tribal governments, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian

tribes, as specified in the Order. As indicated previously, EPA has no information to indicate that any tribal government manufactures or processes the chemical substances covered by this action. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045

This final rule is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because it does not establish an environmental standard intended to mitigate health or safety risks, will not have an annual effect on the economy of $100 million or more, nor does it otherwise have a disproportionate effect on children. This final rule would establish testing and recordkeeping requirements that apply to manufacturers (including importers) and processors of certain chemical substances, and would result in the development of data about those chemical substances that can subsequently be used to assist the Agency and others in determining whether the chemical substances in this final rule present potential risks, allowing the Agency and others to take appropriate action to investigate and mitigate those risks.

H. Executive Order 13211

This final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because it is unlikely to have any significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This final rule involves technical standards that require the use of particular test methods. When the Agency makes findings under TSCA section 4(a), EPA is required by TSCA section 4(b) to include specific standards or test methods that are to be used for the development of the data required in the test rules issued under TSCA section 4. For some of the testing that is required by this rule, EPA is requiring the use of voluntary consensus standards issued by ASTM and ISO which evaluate the same type of toxicity as the TSCA and OECD test methods, where applicable. Copies of the 18 ASTM, ISO, and OECD test methods referenced in § 799.5087(h) of the regulatory text have been placed in the docket for this final rule. You may obtain copies of the ASTM standards from the American Society for Testing and Materials, 100 Bar Harbor Dr., West Conshohocken, PA 19428–2959, and copies of the ISO standards from the International Organization for Standardization, Case Postale, 56 CH–1211 Genève 20 Switzerland. EPA received the required approval from the Director of the Federal Register for the incorporation by reference of the ASTM and ISO standards used in this final rule in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

EPA is not aware of any potentially applicable voluntary consensus standards which evaluate partition coefficient (*n*-octanol/water) generator column, water solubility (column elution and generator column), acute inhalation toxicity, bacterial reverse mutations, *in vivo* mammalian bone marrow chromosomal aberrations, combined repeated dose with reproductive/developmental toxicity screen, repeated dose 28–day oral toxicity screen, or the reproductive developmental toxicity screen which could be considered in lieu of the TSCA test methods, 40 CFR 799.6756, 799.6784, 799.6786, 799.9130, 799.9510, 799.9538, 799.9365, 799.9305, and 799.9355, respectively, upon which the test standards in this final rule are based.

J. Executive Order 12898

This final rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities that require special consideration by the Agency under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). The Agency believes that the information collected under this final rule will assist EPA and others in determining the potential hazards and risks associated with the chemical substances covered by the rule. Although not directly impacting environmental justice-related concerns, this information will better enable the Agency to better protect human health and the environment, including in low-income and minority communities.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Administrative practice and procedure, Reporting and recordkeeping requirements.

40 CFR Part 799

Environmental protection, Chemicals, Hazardous substances, Incorporation by reference, Laboratories, Reporting and recordkeeping requirements.

Dated: December 21, 2010.

Stephen A. Owens,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.,* 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671, 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.,* 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR 1971–1975, Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.,* 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

■ 2. In § 9.1, in the table, revise the entries "Part 725, Part 749, Part 761, Part 790, and Part 799" under the appropriate undesignated center heading indicated below to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
* * * * *	
Reporting Requirements and Review Processes for Microorganisms	
Part 725	2070–0012
* * * * *	
Water Treatment Chemicals	
Part 749	2070–0193
* * * * *	
Polychlorinated Biphenyls (PCBs) Manufacturing, Processing, Distribution in Commerce, and Use Prohibitions	
Part 761	2070–0012
* * * * *	
Procedures Governing Testing Consent Agreements and Test Rules	
Part 790	2070–0033
40 CFR citation	OMB control No.
* * * * *	
Identification of Specific Chemical Substance and Mixture Testing Requirements	
Part 799	2070–0033

* * * * *

PART 799—[AMENDED]

■ 3. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

■ 4. Add § 799.5087 to subpart D to read as follows:

§ 799.5087 Chemical testing requirements for second group of high production volume chemicals (HPV2).

(a) *What substances will be tested under this section?* Table 2 in paragraph (j) of this section identifies the chemical substances that must be tested under this section. For the chemical substances identified as "Class 1" chemical substances in Table 2 in paragraph (j) of this section, the purity of each chemical substance must be 99% or greater, unless otherwise specified in this section. For the chemical substances identified as "Class 2" chemical substances in Table 2 in paragraph (j), a representative form of each chemical substance must be tested. The representative form selected for a given Class 2 chemical substance should meet industry or consensus standards where they exist.

(b) *Am I subject to this section?* (1) If you manufacture (including import) or intend to manufacture, or process or intend to process, any chemical substance listed in Table 2 in paragraph (j) of this section at any time from February 7, 2011 to the end of the test data reimbursement period as defined in 40 CFR 791.3(h), you are subject to this section with respect to that chemical substance.

(2) If you do not know or cannot reasonably ascertain that you manufacture or process a chemical substance listed in Table 2 in paragraph (j) of this section during the time period described in paragraph (b)(1) of this section (based on all information in your possession or control, as well as all information that a reasonable person similarly situated might be expected to possess, control, or know, or could obtain without unreasonable burden), you are not subject to this section with respect to that chemical substance.

(c) *If I am subject to this section, when must I comply with it?* (1)(i) Persons subject to this section are divided into two groups, as set forth in Table 1 of this paragraph: Tier 1 (persons initially required to comply), and Tier 2 (persons not initially required to comply). If you are subject to this section, you must determine if you fall within Tier 1 or Tier 2, based on Table 1 of this paragraph.

TABLE 1—PERSONS SUBJECT TO THE RULE: PERSONS IN TIER 1 AND TIER 2

Persons initially required to comply with this section (Tier 1).	Persons not initially required to comply with this section (Tier 2).
Persons not otherwise specified in column 2 of this table that manufacture (as defined at TSCA section 3(7)) or intend to manufacture a chemical substance included in this section.	Tier 2A. Persons who manufacture (as defined at TSCA section 3(7)) or intend to manufacture a chemical substance included in this section solely as one or more of the following: —As a byproduct (as defined at 40 CFR 791.3(c)); —As an impurity (as defined at 40 CFR 790.3); —As a naturally occurring substance (as defined at 40 CFR 710.4(b)); As a non-isolated intermediate (as defined at 40 CFR 704.3); —As a component of a Class 2 substance (as described at 40 CFR 720.45(a)(1)(i)); —In amounts of less than 500 kg (1,100 lbs) annually (as described at 40 CFR 790.42(a)(4)); or —For research and development (as described at 40 CFR 790.42(a)(5)). B. Persons who process (as defined at TSCA section 3(10)) or intend to process a chemical substance included in this section (see 40 CFR 790.42(a)(2)).

Note: kg—kilogram, TSCA—Toxic Substances Control Act.

(ii) Table 1 of paragraph (c)(1)(i) of this section expands the list of persons in Tier 2, that is, those persons specified in 40 CFR 790.42(a)(2), (a)(4), and (a)(5), who, while legally subject to this section, must comply with the requirements of this section only if directed to do so by EPA under the circumstances set forth in paragraphs (c)(4), (c)(5), (c)(6), (c)(7), and (c)(10) of this section.

(2) If you are in Tier 1 with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, you must, for each test required under this section for that chemical substance, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than February 7, 2011.

(3) If you are in Tier 2 with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, you are considered to have an automatic conditional exemption and you will be required to comply with this section with regard to that chemical substance only if directed to do so by EPA under paragraphs (c)(5), (c)(7), or (c)(10) of this section.

(4) If no person in Tier 1 has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2 in paragraph (j) of this section on or before February 7, 2011, EPA will publish a **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter of intent has been submitted and notify manufacturers in Tier 2A of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(5) If you are in Tier 2A (as specified in Table 1 in paragraph (c) of this section) with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, and if you manufacture, or intend to manufacture, this chemical substance as of February 7, 2011, or within 30 days after publication of the **Federal Register** document described in paragraph (c)(4) of this section, you must, for each test specified for that chemical substance in the document described in paragraph (c)(4) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the document described in paragraph (c)(4) of this section.

(6) If no manufacturer in Tier 1 or Tier 2A has notified EPA of its intent to conduct one or more of the tests required by this section on any chemical substance listed in Table 2 in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(4) of this section, EPA will publish another **Federal Register** document that would specify the test(s) and the chemical substance(s) for which no letter of intent has been submitted, and notify processors in Tier 2B of their obligation to submit a letter of intent to test or to apply for an exemption from testing.

(7) If you are in Tier 2B (as specified in Table 1 in paragraph (c) of this section) with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, and if you process, or intend to process, this chemical substance as of February 7, 2011, or within 30 days after publication of the **Federal Register** document described in paragraph (c)(6) of this section, you must, for each test specified for that chemical substance in the document described in paragraph (c)(6) of this section, either submit to EPA a letter of intent to test or apply to EPA for an exemption from testing. The letter of intent to test or the exemption application must be received by EPA no later than 30 days after publication of the document described in paragraph (c)(6) of this section.

(8) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the chemical substances listed in Table 2 in paragraph (j) of this section within 30 days after the publication of the **Federal Register** document described in paragraph (c)(6) of this section, EPA will notify all manufacturers and processors of those chemical substances of this fact by certified letter or by publishing a **Federal Register** document specifying the test(s) for which no letter of intent has been submitted. This letter or **Federal Register** document will additionally notify all manufacturers and processors that all exemption applications concerning the test(s) have been denied, and will give the manufacturers and processors of the chemical substance(s) an opportunity to take corrective action.

(9) If no manufacturer or processor has notified EPA of its intent to conduct one or more of the tests required by this section for any of the chemical substances listed in Table 2 in paragraph (j) of this section within 30 days after receipt of the certified letter or publication of the **Federal Register** document described in paragraph (c)(8) of this section, all manufacturers and processors subject to this section with respect to that chemical substance who are not already in violation of this section will be in violation of this section.

(10) If a problem occurs with the initiation, conduct, or completion of the required testing or the submission of the required data with respect to a chemical substance listed in Table 2 in paragraph (j) of this section, under the procedures in 40 CFR 790.93 and 790.97, EPA may initiate termination proceedings for all testing exemptions with respect to that chemical substance and may notify persons in Tier 1 and Tier 2 that they are required to submit letters of intent to test or exemption applications within a specified period of time.

(11) If you are required to comply with this section, but your manufacture or processing of, or intent to manufacture or process, a chemical substance listed in Table 2 in paragraph (j) of this section begins after the applicable compliance date referred to in paragraphs (c)(2), (c)(5), or (c)(6) of this section, you must either submit a letter of intent to test or apply to EPA for an exemption. The letter of intent to test or the exemption application must be received by EPA no later than the day you begin manufacture or processing.

(d) *What must I do to comply with this section?* (1) To comply with this section you must either submit to EPA a letter of intent to test, or apply to and obtain from EPA an exemption from testing.

(2) For each test with respect to which you submit to EPA a letter of intent to test, you must conduct the testing specified in paragraph (h) of this section and submit the test data to EPA.

(3) You must also comply with the procedures governing test rule requirements in 40 CFR part 790 (except for those requirements listed in this paragraph as not applicable to this section), including the submission of letters of intent to test or exemption applications, the conduct of testing, and the submission of data; 40 CFR Part 792—Good Laboratory Practice Standards; and this section. The following provisions of 40 CFR part 790 do not apply to this section: Paragraphs (a), (d), (e), and (f) of § 790.45; paragraph (a)(2) and paragraph (b) of § 790.80; § 790.82(e)(1); § 790.85; and § 790.48.

(e) *If I do not comply with this section, when will I be considered in violation of it?* You will be considered in violation of this section as of 1 day after the date by which you are required to comply with this section.

(f) *How are EPA's data reimbursement procedures affected for purposes of this section?* If persons subject to this section are unable to agree on the amount or method of reimbursement for test data development for one or more chemical substances included in this section, any person may request a hearing as described in 40 CFR part 791. In the determination of fair reimbursement shares under this section, if the hearing officer chooses to use a formula based on production volume, the total production volume amount will include amounts of a chemical substance produced as an impurity.

(g) *Who must comply with the export notification requirements?* Any person who exports, or intends to export, a chemical substance listed in Table 2 in paragraph (j) of this section is subject to 40 CFR part 707, subpart D.

(h) *How must I conduct my testing?* (1) The tests that are required for each chemical substance are indicated in Table 2 in paragraph (j) of this section. The test methods that must be followed are provided in Table 3 in paragraph (j) of this section. You must proceed in accordance with these test methods as required according to Table 3 in paragraph (j) of this section, or as appropriate if more than one alternative is allowed according to Table 3 in paragraph (j) of this section. Included in Table 3 in paragraph (j) of this section

are the following 18 test methods which are incorporated by reference:

(i) Standard Test Method for Relative Initial and Final Melting Points and the Melting Range of Organic Chemicals, ASTM E 324–99, approved September 10, 1999.

(ii) Standard Test Method for Partition Coefficient (*N*-Octanol/Water) Estimation by Liquid Chromatography, ASTM E 1147–92 (Reapproved 2005), approved August 1, 2005.

(iii) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians, ASTM E 729–96 (Reapproved 2007), approved October 1, 2007.

(iv) Standard Test Method for Measurements of Aqueous Solubility, ASTM E 1148–02 (Reapproved 2008), approved February 1, 2008.

(v) Standard Test Method for Estimating Acute Oral Toxicity in Rats, ASTM E 1163–98 (Reapproved 2002), approved October 10, 2002.

(vi) Standard Guide for Conducting Daphnia Magna Life-Cycle Toxicity Tests, ASTM E 1193–97 (Reapproved 2004), approved April 1, 2004.

(vii) Standard Guide for Conducting Static Toxicity Tests with Microalgae, ASTM E 1218–04^{e1}, approved April 1, 2004.

(viii) Standard Test Method for Vapor Pressure of Liquids by Ebulliometry, ASTM E 1719–05, approved March 1, 2005.

(ix) Standard Test Method for Determining Ready, Ultimate, Biodegradability of Organic Chemicals in a Sealed Vessel CO_2 Production Test. ASTM E 1720–01 (Reapproved 2008), approved February 1, 2008.

(x) Standard Test Method for Determining Vapor Pressure by Thermal Analysis, ASTM E 1782–08, approved March 1, 2008.

(xi) Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Method by Analysis of Inorganic Carbon in Sealed Vessels (CO_2 Headspace Test). First Edition, March 15, 1999. ISO 14593:1999(E).

(xii) Water Quality—Evaluation in an Aqueous Medium of the "Ultimate" Aerobic Biodegradability of Organic Compounds—Method by Analysis of Dissolved Organic Carbon (DOC). Second Edition, September 15, 1994. ISO 7827:1994(E).

(xiii) Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium by Determination of Oxygen Demand in a Closed Respirometer. Second Edition, August 1, 1999. ISO 9408:1999(E).

(xiv) Water Quality—Evaluation of Ultimate Aerobic Biodegradability of Organic Compounds in Aqueous Medium—Carbon Dioxide Evolution Test. Second Edition, March 1, 1999. ISO 9439:1999(E).

(xv) Water Quality—Evaluation in an Aqueous Medium of The "Ultimate" Aerobic Biodegradability of Organic Compounds—Method by Analysis of Biochemical Oxygen Demand (Closed Bottle Test). First Edition, October 15, 1994. ISO 10707:1994(E).

(xvi) Water Quality—Evaluation in an Aqueous Medium of the Ultimate Aerobic Biodegradability of Organic Compounds—Determination of Biochemical Oxygen Demand in a Two-Phase Closed Bottle Test. First Edition, February 1, 1997. ISO 10708:1997(E).

(xvii) Water Quality—Guidance for the Preparation and Treatment of Poorly Water-Soluble Organic Compounds for the Subsequent Evaluation of Their Biodegradability in an Aqueous Medium. First Edition, August 15, 1995. ISO 10634:1995(E).

(xviii) Guideline for the Testing of Chemicals: Melting Point/Melting Range. OECD 102. July 27, 1995.

(2) The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies of the ASTM test methods from the American Society for Testing and Materials, 100 Bar Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, telephone number: (610) 832–9585, web address: *http://www.astm.org;* copies of the ISO test methods from the International Organization for Standardization, 1, ch. de la Voie-Creuse, Case postale, 56 CH–1211 Geneve 20 Switzerland, telephone number: +41 22 749 01 11, web address: *http://www.iso.org;* and a copy of the OECD guideline from the Organization for Economic Cooperation and Development, 2, rue André Pascal,75775 Paris Cedex 16 France, telephone number: +33 1 45 24 82 00, web address: *http://www.oecd.org.* You may inspect each test method and guideline at the EPA Docket Center, EPA West, Rm. B102, 1301 Constitution Ave., NW., Washington, DC 20004, telephone number: (202) 566–1744, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

(i) *Reporting requirements.* A final report for each specific test for each subject chemical substance must be received by EPA by March 7, 2012, unless an extension is granted in writing pursuant to 40 CFR 790.55. A robust summary of the final report for each specific test should be submitted in addition to and at the same time as the final report. The term "robust summary" is used to describe the technical information necessary to adequately describe an experiment or study and includes the objectives, methods, results, and conclusions of the full study report which can be either an experiment or in some cases an estimation or prediction method. Guidance for the compilation of robust summaries is described in a document entitled "Draft Guidance on Developing Robust Summaries" which is available on-line: *http://www.epa.gov/chemrtk/pubs/general/robsumgd.htm.*

(j) *Designation of specific chemical substances and testing requirements.* The chemical substances identified by chemical name, Chemical Abstract Service Registry Number (CASRN), and class in Table 2 of this paragraph must be tested in accordance with the requirements designated in Tables 2 and 3 of this paragraph, and the requirements described in 40 CFR part 792—Good Laboratory Practice Standards:

TABLE 2—CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS

CASRN	Chemical name	Class	Required tests/(See table 3 of this section)
75–07–0	Acetaldehyde	1	C2, F2.
78–11–5	1,3-Propanediol, 2,2-bis[(nitrooxy)methyl]-, dinitrate (ester).	1	C4.
84–65–1	9,10-Anthracenedione	1	C6.
89–32–7	1H,3H-Benzo[1,2-c:4,5-c′]difuran-1,3,5,7-tetrone	1	A3, A4, A5, B, C1, D, E1, F1.
110–44–1	2,4-Hexadienoic acid, (E,E)-	1	C6.
118–82–1	Phenol, 4,4′-methylenebis[2,6-bis(1,1-dimethylethyl)-	1	C1.
119–61–9	Methanone, diphenyl-	1	B, C2.

TABLE 2—CHEMICAL SUBSTANCES AND TESTING REQUIREMENTS—Continued

CASRN	Chemical name	Class	Required tests/(See table 3 of this section)
144–62–7	Ethanedioic acid	1	A1, A2, A3, A5, B, C1, E2.
149–44–0	Methanesulfinic acid, hydroxy-, monosodium salt	1	E1.
2524–04–1	Phosphorochloridothioic acid, O,O-diethyl ester	1	A1, A2, A3, A4, A5, B, C1, E1, E2, F2.
4719–04–4	1,3,5-Triazine-1,3,5(2H,4H,6H)-triethanol	1	C6.
6381–77–7	D-erythro-hex-2-enonic acid, gamma.-lactone, monosodium salt.	1	A4, B, C1.
31138–65–5	D-gluco-heptonic acid, monosodium salt, (2.xi.)-	1	A1, A2, A4, A5, B, C1, D, E1, E2, F1.
66241–11–0	C.I. Leuco Sulphur Black 1	2	A1, A2, A3, A4, A5, B, C1, D, E1, E2, F1.
68187–76–8	Castor oil, sulfated, sodium salt	2	A1, A2, C1, D, E1, E2, F1.
68187–84–8	Castor oil, oxidized	2	A1, A2, B, E1, E2, F1.
68479–98–1	Benzenediamine, ar,ar-diethyl-ar-methyl-	1	A1, A3, A4, A5, C1, E1, E2, F1.
68527–02–6	Alkenes, $C_{12–24}$, chloro	2	A1, A2, A3, A4, A5, B, C1, E2, F2.
68647–60–9	Hydrocarbons, C > 4	2	A2, A3, A5, B, C1, D, E1, E2, F1.

Note: CASRN = Chemical Abstract Service Registry Number.

TABLE 3—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2 OF THIS PARAGRAPH

[Note: The ASTM and ISO test methods and the OECD guideline required in this paragraph are incorporated by reference; see paragraph (h) of this section.]

Testing category	Test symbol	Test requirements and references	Special conditions
Physical/chemical properties.	A	1. Melting Point: American Society for Testing and Materials (ASTM) E 324–99 (capillary tube), if a Freezing Point: Organization for Economic Co-operation and Development (OECD) 102 (melting point/melting range). 2. Boiling Point: ASTM E 1719–05 (ebulliometry) ... 3. Vapor Pressure: ASTM E 1782–08 (thermal analysis). 4. n-Octanol/Water Partition Coefficient (log 10 basis) or log K_{OW}: (See Special Conditions for the log K_{OW} test requirement and select the appropriate method to use, if any, from those listed in this column.). Method A: 40 CFR 799.6755 (shake flask) ..... Method B: ASTM E 1147–92 (Reapproved 2005) (liquid chromatography). Method C: 40 CFR 799.6756 (generator column) 5. Water Solubility: (See Special Conditions for the water solubility test requirement and select the appropriate method to use, if any, from those listed in this column.). Method A: ASTM E 1148–02 (Reapproved 2008) (shake flask). Method B: 40 CFR 799.6784 (shake flask) ..... Method C: 40 CFR 799.6784 (column elution) .... Method D: 40 CFR 799.6786 (generator column)	n-Octanol/water Partition Coefficient (log 10 basis) or log K_{OW}: Which method is required, if any, is determined by the test substance's estimated[i] log K_{OW} as follows: log K_{OW} < 0: No testing required. log K_{OW} range 0–1: Method A or B. log K_{OW} range > 1–4: Method A, B, or C. log K_{OW} range > 4–6: Method B or C. log K_{OW} > 6: Method C. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted at pH 7. Water Solubility: Which method is required, if any, is determined by the test substance's estimated[ii] water solubility. Test sponsors must provide in the final study report the underlying rationale for the method and pH selected. In order to ensure environmental relevance, EPA highly recommends that the selected study be conducted starting at pH 7. > 5,000 milligram/Liter (mg/L): Method A or B. > 10 mg/L–5,000 mg/L: Method A, B, C, or D. > 0.001 mg/L–10 mg/L: Method C or D. ≤ 0.001 mg/L: No testing required.
Environmental fate and pathways—ready biodegradation.	B	For B, consult International Organization for Standardization (ISO) 10634:1995(E) for guidance, and choose one of the methods listed in this column:. 1. ASTM E 1720–01 (Reapproved 2008) (sealed vessel CO_2 production test) OR. 2. ISO 14593:1999(E) (CO_2 headspace test) OR ... 3. ISO 7827:1994(E) (analysis of DOC) OR ..... 4. ISO 9408:1999(E) (determination of oxygen demand in a closed respirometer) OR. 5. ISO 9439:1999(E) (CO_2 evolution test) OR. 6. ISO 10707:1994(E) (closed bottle test) OR. 7. ISO 10708:1997(E) (two-phase closed bottle test).	Which method is required, if any, is determined by the test substance's physical and chemical properties, including its water solubility. ISO 10634:1995(E) provides guidance for selection of an appropriate test method for a given test substance. Test sponsors must provide in the final study report the underlying rationale for the method selected.

TABLE 3—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2 OF THIS PARAGRAPH—Continued

[Note: The ASTM and ISO test methods and the OECD guideline required in this paragraph are incorporated by reference; see paragraph (h) of this section.]

Testing category	Test symbol	Test requirements and references	Special conditions
Aquatic toxicity	C1	For C1, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions.. Test Group 1 for C1: ..... 1. Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). 2. Acute Toxicity to Daphnia: ASTM E 729–96 (Reapproved 2007). 3. Toxicity to Plants (Algae): ASTM E 1218–04 e1 .. Test Group 2 for C1: ..... 1. Chronic Toxicity to Daphnia: ASTM E 1193–97 (Reapproved 2004). 2. Toxicity to Plants (Algae): ASTM E 1218—04 e1	The following are the special conditions for C1, C2, C3, C4, C5, and C7 testing; there are no special conditions for C6. Which test group is required is determined by the test substance's measured log K_{OW} as obtained under Test Category A, or using an existing measured log K_{OW}.[iii] If log K_{OW} < 4.2: Test Group 1 is required. If log $K_{OW} \geq$ 4.2: Test Group 2 is required
	C2	For C2, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions.. Test Group 1 for C2:. 1. Acute Toxicity to Daphnia: ASTM E 729–96 (Reapproved 2007). 2. Toxicity to Plants (Algae): ASTM E 1218–04 e1. Test Group 2 for C2:. 1. Chronic Toxicity to Daphnia: ASTM E 1193–97 (Reapproved 2004). 2. Toxicity to Plants (Algae): ASTM E 1218–04 e1.	
	C3	For C3, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions.. Test Group 1 for C3:. 1. Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). 2. Toxicity to Plants (Algae): ASTM E 1218–04 e1. Test Group 2 for C3:. 1. Chronic Toxicity to Daphnia: ASTM E 1193–97 (Reapproved 2004). 2. Toxicity to Plants (Algae): ASTM E 1218–04 e1.	
	C4	For C4, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions.. Test Group 1 for C4:. 1. Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). 2. Acute Toxicity to Daphnia: ASTM E 729–96 (Reapproved 2007). Test Group 2 for C4:. 1. Chronic Toxicity to Daphnia: ASTM E 1193–97 (Reapproved 2004).	
	C5	For C5, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions.. Test Group 1 for C5:. 1. Acute Toxicity to Daphnia: ASTM E 729–96 (Reapproved 2007). Test Group 2 for C5:. 1. Chronic Toxicity to Daphnia: ASTM E 1193–97 (Reapproved 2004).	
	C6	Toxicity to Plants (Algae): ASTM E 1218–04 e1.	
.....	C7	For C7, Test Group 1 or Test Group 2 listed in this column must be used to fulfill the testing requirements—See Special Conditions.. Test Group 1 for C7:. 1. Acute Toxicity to Fish: ASTM E 729–96 (Reapproved 2007). Test Group 2 for C7:. 1. Chronic Toxicity to Daphnia: ASTM E 1193–97 (Reapproved 2004).	

TABLE 3—KEY TO THE TEST REQUIREMENTS DENOTED BY ALPHANUMERIC SYMBOLS IN TABLE 2 OF THIS PARAGRAPH—Continued

[Note: The ASTM and ISO test methods and the OECD guideline required in this paragraph are incorporated by reference; see paragraph (h) of this section.]

Testing category	Test symbol	Test requirements and references	Special conditions
Mammalian toxicity—acute	D	See special conditions for this test requirement and select the method that must be used from those listed in this column.. Method A: Acute Inhalation Toxicity (rat): 40 CFR 799.9130. Method B: EITHER: ..... 1. Acute (Up/Down) Oral Toxicity (rat): ASTM E 1163–98 (Reapproved 2002). OR ..... 2. Acute (Up/Down) Oral Toxicity (rat): 40 CFR 799.9110(d)(1)(i)(A).	Which testing method is required is determined by the test substance's physical state at room temperature (25 °C). For those test substances that are gases at room temperature, Method A is required; otherwise, use either of the two methods listed under Method B. In Method B, 40 CFR 799.9110(d)(1)(i)(A) refers to the OECD 425 Up/Down Procedure.[iv] Estimating starting dose for Method B: Data from the neutral red uptake basal cytotoxicity assay[v] using normal human keratinocytes or mouse BALB/c 3T3 cells may be used to estimate the starting dose.
Mammalian toxicity—genotoxicity.	E1	Bacterial Reverse Mutation Test (in vitro): 40 CFR 799.9510.	None
	E2	Conduct any one of the following three tests for chromosomal damage: In vitro Mammalian Chromosome Aberration Test: 40 CFR 799.9537. OR ..... Mammalian Bone Marrow Chromosomal Aberration Test (in vivo in rodents: mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9538. OR ..... Mammalian Erythrocyte Micronucleus Test [sampled in bone marrow] (in vivo in rodents: Mouse (preferred species), rat, or Chinese hamster): 40 CFR 799.9539.	Persons required to conduct testing for chromosomal damage are encouraged to use the in vitro Mammalian Chromosome Aberration Test (40 CFR 799.9537) to generate the needed data unless known chemical properties (e.g., physical/chemical properties, chemical class characteristics) preclude its use. A subject person who uses one of the in vivo methods instead of the in vitro method to address a chromosomal damage test requirement must submit to EPA a rationale for conducting that alternate test in the final study report.
Mammalian toxicity—repeated dose/reproduction/developmental.	F1	Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9365. OR ..... Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355. AND ..... Repeated Dose 28–Day Oral Toxicity Study in rodents: 40 CFR 799.9305.	Where F1 is required, EPA recommends use of the Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (40 CFR 799.9365). However, there may be valid reasons to test a particular chemical using both 40 CFR 799.9355 and 40 CFR 799.9305 to fill Mammalian Toxicity—Repeated Dose/Reproduction/Developmental data needs. A subject person who uses the combination of 40 CFR 799.9355 and 40 CFR 799.9305 in place of 40 CFR 799.9365 must submit to EPA a rationale for conducting these alternate tests in the final study reports. Where F2 or F3 is required, no rationale for conducting the required test need be provided in the final study report.
	F2	Reproduction/Developmental Toxicity Screening Test: 40 CFR 799.9355.	
	F3	Repeated Dose 28–Day Oral Toxicity Study in rodents: 40 CFR 799.9305.	

[i] EPA recommends, but does not require, that log K_{OW} be quantitatively estimated prior to initiating this study. One method, among many similar methods, for estimating log K_{OW} is described in the article entitled "Atom/Fragment Contribution Method for Estimating Octanol-Water Partition Coefficients" by W.M. Meylan and P.H. Howard in the Journal of Pharmaceutical Sciences. 84(1):83–92. January 1992. This reference is available in docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC 20004, telephone number: (202) 566–1744, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

[ii] EPA recommends, but does not require, that water solubility be quantitatively estimated prior to initiating this study. One method, among many similar methods, for estimating water solubility is described in the article entitled "Improved Method for Estimating Water Solubility From Octanol/Water Partition Coefficient" by W.M. Meylan, P.H. Howard, and R.S. Boethling in Environmental Toxicology and Chemistry. 15(2):100–106. 1996. This reference is available in docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC 20004, telephone number: (202) 566–1744, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

[iii] Chemical substances that are dispersible in water may have log K_{OW} values greater than 4.2 and may still be acutely toxic to aquatic organisms. Test sponsors who wish to conduct Test Group 1 studies on such chemicals may request a modification to the test standard as described in 40 CFR 790.55. Based upon the supporting rationale provided by the test sponsor, EPA may allow an alternative threshold or method be used for determining whether acute or chronic aquatic toxicity testing be performed for a specific substance.

[iv] The OECD 425 Up/Down Procedure, revised by OECD in December 2001, is available in docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC 20004, telephone number: (202) 566–1744, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

[v] The neutral red uptake basal cytotoxicity assay, which may be used to estimate the starting dose for the mammalian toxicity-acute endpoint, is available in docket ID number EPA–HQ–OPPT–2007–0531 at the EPA Docket Center, Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC 20004, telephone number: (202) 566–1744, from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

[FR Doc. 2010–33313 Filed 1–6–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2010–0003]

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: Base (1% annual-chance) Flood Elevations (BFEs) and modified BFEs are made final for the communities listed below. The BFEs and modified BFEs are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing BFEs and modified BFEs for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated in the table below.

ADDRESSES: The final BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the modified BFEs for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Federal Insurance and Mitigation Administrator has resolved any appeals resulting from this notification.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community. The BFEs and modified BFEs are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act. This final rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This final rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This final rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

■ 1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

■ 2. The tables published under the authority of § 67.11 are amended as follows:

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Stephenson County, Illinois, and Incorporated Areas Docket No.: FEMA–B–1087			
Indian Creek	Approximately 0.61 mile upstream of State Route 73	+782	Unincorporated Areas of Stephenson County.
	Approximately 0.78 mile upstream of State Route 73	+782	
Pecatonica River	Approximately 1.2 miles downstream of North Rock City Road.	+749	Village of Ridott.
	Approximately 1.93 miles upstream of North Rock City Road.	+754	
Pecatonica River	Approximately 0.43 mile downstream of State Route 75 (Stephenson Street).	+762	City of Freeport.
	Approximately 4.0 miles upstream of State Route 26	+767	

Flooding source(s)	Location of referenced elevation	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL) Modified	Communities affected
Pecatonica River	Approximately 1.61 miles upstream of West McConnell Road.	+779	Unincorporated Areas of Stephenson County.
	At the Illinois/Wisconsin State boundary	+782	
Yellow Creek	Approximately 400 feet downstream of Pearl City Road	+814	Unincorporated Areas of Stephenson County.
	Approximately 0.49 mile upstream of Pearl City Road	+815	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Freeport
Maps are available for inspection at City Hall, 230 West Stephenson Street, Freeport, IL 61032.

Unincorporated Areas of Stephenson County
Maps are available for inspection at the Stephenson County Courthouse, 15 North Galena Avenue, Freeport, IL 61032.

Village of Ridott
Maps are available for inspection at the Village Hall, 200 East 3rd Street, Ridott, IL 61607.

Moniteau County, Missouri, and Incorporated Areas
Docket No.: FEMA–B–1087

Missouri River	Approximately 3,000 feet upstream of the Cole County boundary.	+574	City of Lupus, Unincorporated Areas of Moniteau County
	Approximately 375 feet downstream of the Cooper County boundary.	+587	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Lupus
Maps are available for inspection at 3750 Main Street, Lupus, MO 65046.

Unincorporated Areas of Moniteau County.
Maps are available for inspection at 200 East Main Street, California, MO 65018.

Highland County, Ohio, and Incorporated Areas
Docket No.: FEMA–B–1085

Clear Creek	Approximately 1.4 miles upstream of State Route 138	+938	City of Hillsboro, Unincorporated Areas of Highland County.
	Approximately 2.0 miles upstream of State Route 138	+943	
Turtle Creek	At the confluence with East Fork Little Miami River	+985	Unincorporated Areas of Highland County.
	Just downstream of Sycamore Street	+991	
	Approximately 1,840 feet upstream of Sycamore Street	+996	
	Approximately 0.4 mile upstream of Sycamore Street	+996	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

ADDRESSES

City of Hillsboro
Maps are available for inspection at City Hall, 130 North High Street, Hillsboro, OH 45133.

Unincorporated Areas of Highland County
Maps are available for inspection at 119 Governor Foraker Place, Suite 206, Highland, OH 45133.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: December 27, 2010.

Sandra K. Knight,

Deputy Federal Insurance and Mitigation Administrator, Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2011–131 Filed 1–6–11; 8:45 am]

BILLING CODE 9110–12–P

Proposed Rules

Federal Register
Vol. 76, No. 5
Friday, January 7, 2011

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 531 and 575

RIN 3206–AM13

Pay Under the General Schedule and Recruitment, Relocation, and Retention Incentives

AGENCY: U.S. Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing proposed regulations to improve oversight of group recruitment incentive determinations and all retention incentives; add succession planning to the list of factors that an agency may consider before approving a retention incentive; provide that OPM may require data on recruitment, relocation, and retention incentives from agencies on an annual basis; and make additional minor clarifications and corrections.

DATES: Comments must be received on or before March 8, 2011.

ADDRESSES: You may submit comments, identified by RIN number "3206–AM13," using either of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Jerome D. Mikowicz, Deputy Associate Director, Pay and Leave, Employee Services, U.S. Office of Personnel Management, Room 7H31, 1900 E Street, NW., Washington, DC 20415–8200.

FOR FURTHER INFORMATION CONTACT: Carey Jones by telephone at (202) 606–2858; by fax at (202) 606–0824; or by e-mail at *pay-leave-policy@opm.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Office of Personnel Management (OPM) is issuing proposed regulations to improve oversight of group recruitment incentive determinations and all retention incentives; add succession planning to the list of factors that an agency may consider before approving a retention incentive; provide that OPM may require data on recruitment, relocation, and retention incentives from agencies on an annual basis; and make additional minor clarifications and corrections.

Administration and Oversight of Recruitment, Relocation, and Retention Incentives

In May 2009, OPM announced a project to review and improve the administration and oversight of recruitment, relocation, and retention incentives (3Rs). In a memorandum to heads of executive departments and agencies, OPM asked agencies to review their 3Rs programs to ensure that ongoing and new authorizations for payments to employees are used only when necessary to support the agency's mission and recommended agencies review all retention incentives at least annually. In July 2009, OPM asked each agency to review and, if needed, update its 3Rs plans, as well as approval and internal monitoring procedures to ensure they meet the requirements in 5 CFR part 575, subparts A, B, and C. In August 2009, OPM convened a work group of compensation experts from the 12 Federal agencies that used the greatest number of 3Rs in 2007 to develop recommendations for improving the administration and oversight of the 3Rs authorities. The work group recommended that OPM issue proposed regulations to require agencies to review group recruitment incentives and all retention incentives at least annually to determine whether they should be modified or discontinued based on new or changed conditions. This will help agencies ensure that recurring recruitment or retention incentive authorizations for the same group of employees (or individual employees, in the case of retention incentives) are appropriate. These proposed regulations support the recommendations made by OPM in the May 2009 memo and by the work group.

Recruitment Incentives

Under 5 CFR 575.105, an agency may target groups of similar positions that have been difficult to fill in the past or that are likely to be difficult to fill in the future and may make the determination to offer a recruitment incentive to newly-appointed employees on a group basis. OPM proposes revising 5 CFR 575.105(b) to require that each agency review each decision to target a group of similar positions at least annually to determine whether the positions are still likely to be difficult to fill. An authorized agency official must certify this determination in writing. An agency that determines a group of similar positions is no longer likely to be difficult to fill may no longer offer a group recruitment incentive to newly-appointed employees of that group.

Relocation Incentives

As provided in 5 U.S.C. 5753(b)(2)(B)(ii)(II), an agency may pay a relocation incentive only if the employee must relocate to accept a position in a different geographic area. In order to make this determination, the regulations in 5 CFR 575.205(b) require that an employee establish a residence in the new geographic area before the agency may pay a relocation incentive to the employee. OPM proposes revising 5 CFR 575.205(b) by adding a requirement that an employee maintain residency in the new geographic area for the duration of the service agreement in order to receive relocation incentive payments. OPM also proposes revising 5 CFR 575.211(b) to require that an authorized agency official terminate a relocation incentive service agreement if an employee fails to maintain residency in the new geographic area for the duration of the service agreement. These changes will make the regulations more consistent with the requirement in the law that an employee must relocate to receive a relocation incentive.

Retention Incentives

Annual Review

OPM's regulations in 5 CFR 575.311 are clear that each agency is responsible for terminating retention incentives when conditions change such that the original determination to pay the incentive no longer applies or when payment is no longer warranted. Agencies are currently required under § 575.311(f) to review each determination to pay a retention incentive without a service agreement at least annually to determine whether the payment is still warranted. OPM proposes revising § 575.311(a) to require that agencies also review each determination to pay a retention incentive that is subject to a service

agreement at least annually to determine whether the original determination to pay the retention incentive still applies or whether payment is still warranted and certify this determination in writing. This will ensure all retention incentive authorizations are reviewed at least annually, whether associated with a service agreement or not.

Succession Planning

An agency must consider the factors in 5 CFR 575.306(b), as applicable to the case at hand, in determining whether the unusually high or unique qualifications of an employee or a special need of the agency for an employee's services makes it essential to retain the employee and that the employee would be likely to leave the Federal service in the absence of a retention incentive. OPM proposes adding another factor for agencies to consider as follows: "The quality and availability of the potential sources of employees that are identified in the agency's succession plan, who possess the competencies required for the position, and who, with minimal training, cost, and disruption of service to the public, could perform the full range of duties and responsibilities of the employee's position at the level performed by the employee."

Succession planning is a critical success factor in strategic workforce analysis, planning, and decision making. OPM currently requires each agency to establish a succession plan to fill supervisory and managerial positions. (*See* 5 CFR 412.201 and 250.202(c)(2).) In addition, OPM's Human Capital Assessment and Accountability Framework advises that a succession plan should include specific goals and leadership positions needed, target positions and key leadership competencies, potential sources of talent that best support the agency's mission and culture, and recruitment or development strategies needed to ensure availability of well-qualified staff to fill leadership positions at all levels. Agencies currently have the flexibility to consider their succession planning efforts in the decision process for awarding retention incentives as "other supporting factors" under 5 CFR 575.306(b)(8). However, specifically listing the factor in this section of the regulations will strengthen the relationship between succession planning and retention incentives.

OPM is also taking this opportunity to correct some erroneous references in § 575.305(c).

Employee Eligibility

Currently, Senior Executive Service (SES) members paid under 5 U.S.C. 5383 are eligible for recruitment, relocation, and retention incentives under 5 CFR 575.103(a)(3), 575.203(a)(3), and 575.303(a)(3), unless the SES member is excluded under one of the conditions in 5 CFR 575.104, 575.204, and 575.304. Some of the exclusions are established under 5 U.S.C. 5753(a)(2) and 5754(a)(2), while the others are established under regulatory authority consistent with the intent of the law. All of the exclusions in the law and regulations are political appointees or individuals whose political appointments are pending. For example, an agency may not pay a recruitment, relocation, or retention incentive to an employee in a position to which the individual is appointed by the President with or without the advice and consent of the Senate.

An agency made OPM aware of an extremely rare situation in which an individual was appointed by the President, without the advice and consent of the Senate, to a position in the career SES. The agency had properly determined that the position is a career reserved position as that term is defined in 5 U.S.C. 3132. Such an employee should be eligible for a recruitment, relocation, or retention incentive because the employee serves as a career appointee while in the Presidential appointment. A career SES member who accepts a Presidential appointment and no longer serves as a career appointee under the Presidential appointment would not be eligible for recruitment, relocation, or retention incentives. Note also that coverage under the 3Rs authorities is not among the elections available to an individual under 5 CFR part 317, subpart H. Therefore, OPM proposes revising 5 CFR 575.104(d)(1), 575.204(d)(1), and 575.304(d)(1) to clarify that an agency may pay a recruitment, relocation, or retention incentive to an employee in an SES position in which the individual serves as a career appointee, even if the member is appointed by the President without the advice and consent of the Senate.

OPM also proposes revising 5 CFR 575.104(d), 575.204(d), and 575.304(d) to clarify that all individuals whose SES limited appointments are cleared through the White House Office of Presidential Personnel are ineligible for 3Rs payments. Limited term and limited emergency SES appointments may be political appointments if made to positions that are political in character (*e.g.,* established for an individual pending Presidential appointment, for political transition purposes, or for other political purposes of the agency or Administration) and should be excluded from coverage as other political positions are excluded from coverage.

Another agency recently asked OPM whether a limited term or limited emergency SES member could receive a recruitment incentive if selected for a career SES position. Recruitment incentives may be paid to an employee who is "newly appointed" to the Federal Government, as that term is defined in 5 CFR 575.102. The definition includes the first appointment (regardless of tenure) as an employee of the Federal Government, an appointment following a break in service of at least 90 days from a previous appointment as an employee of the Federal Government, or, in certain cases, an appointment following a break in service of less than 90 days from a previous appointment as an employee of the Federal Government. OPM proposes adding that a break in service of at least 90 days would not be required if the previous appointment was a position to which the individual was appointed as an SES limited term appointee or limited emergency appointee (except as described in the next paragraph). This would be consistent with how a time-limited appointment in the competitive or excepted service is not subject to the 90-day break in service requirement.

OPM also proposes clarifying that an employee would be required to have a break in service of at least 90 days from an appointment that is ineligible for recruitment incentives as provided in 5 CFR 575.104 even if the appointment is otherwise covered by an exception in the definition of "newly appointed" in 5 CFR 575.102. For example, as proposed, an SES limited term appointee or limited emergency appointee when the appointment must be cleared through the White House Office of Presidential Personnel would be required to have at least a 90-day break in service before becoming eligible for a recruitment incentive, but an SES limited term appointee or limited emergency appointee when the appointment does not need to be cleared through the White House Office of Presidential Personnel would not be required to have at least a 90-day break in service before becoming eligible for a recruitment incentive. OPM also proposes making similar revisions to the superior qualifications and special needs pay-setting authority regulations in 5 CFR 531.212(a)(3).

Reports

Section 101(c) of the Federal Workforce Flexibility Act of 2004 (Pub. L. 108–411, October 30, 2004) required OPM to submit an annual report to the Committee on Governmental Affairs of the Senate and the Committee on Government Reform in the House of Representatives on the operation of the 3Rs authorities for each of the first 5 years in which the amended authorities were in effect (*i.e.,* 2005 to 2009). Sections 575.113(b), 575.213(b), 575.313(b), and 575.315(i) require agencies to submit specific information and data to OPM for this annual report. While OPM will no longer be required to submit a report to Congress on agencies' use of the 3Rs authorities in calendar year 2010 and subsequent calendar years, OPM has found the annual report to be very informative concerning Governmentwide use of the 3Rs. We also learned in the interagency work group that met in August 2009 (see Administration and Oversight of Recruitment, Relocation, and Retention Incentives section of this **SUPPLEMENTARY INFORMATION**) that the 3Rs report may help agencies understand the nature and trends of their own 3Rs use. OPM is also able to compare the data agencies report to OPM for the report to Congress to the data agencies report to OPM's central data systems under 5 CFR 9.2 and follow up with agencies concerning the accuracy of the data. Therefore, OPM proposes to amend sections 575.113(b), 575.213(b), 575.313(b), and 575.314(i) (as redesignated in these proposed regulations) to remove references to OPM's report to Congress and provide that OPM may require that each agency submit a report to OPM on its use of incentives in the previous calendar year. The proposed regulations would also allow OPM to exempt an agency (or part of an agency) from all or any part of any reporting requirement if OPM has determined that the incentive data submitted to OPM's central data systems under 5 CFR 9.2 is accurate and sufficient for our Governmentwide role of monitoring and administering the 3Rs.

Recruitment, Relocation, and Retention Payments Authorized Before May 1, 2005

Under section 101(d)(2) of Public Law 108–411 and 5 CFR 575.114 and 575.214, a recruitment or relocation bonus service agreement that was authorized under 5 U.S.C. 5753 and 5 CFR part 575, subparts A and B, before May 1, 2005, remained in effect until its expiration, subject to the law and regulations applicable to recruitment and relocation bonuses before May 1, 2005. We propose removing §§ 575.114 and 575.214, as such recruitment and relocation bonus service agreements have likely expired.

Under section 101(d)(3) of Public Law 108–411 and 5 CFR 575.314, retention allowances that were authorized under 5 U.S.C. 5754 and 5 CFR part 575, subpart C, before May 1, 2005, had to continue to be paid until the retention allowance was reauthorized or terminated, but not later than April 30, 2006, and were subject to the law and regulations applicable to retention allowances before May 1, 2005. We propose removing § 575.314 and redesignating § 575.315 as § 575.314 because the April 30, 2006 deadline has been met.

E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

List of Subjects in 5 CFR Parts 531 and 575

Government employees, Law enforcement officers, Wages.

U.S. Office of Personnel Management.

John Berry,

Director.

Accordingly, OPM is proposing to amend 5 CFR parts 531 and 575 as follows:

PART 531—PAY UNDER THE GENERAL SCHEDULE

1. The authority citation for part 531 continues to read as follows:

Authority: 5 U.S.C. 5115, 5307, and 5338; sec. 4 of Public Law 103–89, 107 Stat. 981; and E.O. 12748, 56 FR 4521, 3 CFR, 1991 Comp., p. 316; Subpart B also issued under 5 U.S.C. 5303(g), 5305, 5333, 5334(a) and (b), and 7701(b)(2); Subpart D also issued under 5 U.S.C. 5335 and 7701(b)(2); Subpart E also issued under 5 U.S.C. 5336; Subpart F also issued under 5 U.S.C. 5304 and 5305; E.O. 12883, 58 FR 63281, 3 CFR, 1993 Comp., p. 682; and E.O. 13106, 63 FR 68151, 3 CFR, 1998 Comp., p. 224.

Subpart B—Determining Rate of Basic Pay

2. In § 531.212—

a. Amend paragraph (a)(1)(ii) by removing word "and" and adding "or" in its place;

b. Revise paragraph (a)(3); and

c. Add paragraph (a)(5).

The revision and addition read as follows:

§ 531.212 Superior qualifications and special needs pay-setting authority.

(a) * * *

(3) Except as provided in paragraph (a)(5) of this section, an agency may use the superior qualifications and special needs pay-setting authority for a reappointment without requiring a 90-day break in service if the candidate's civilian employment with the Federal Government during the 90-day period immediately preceding the appointment was limited to one or more of the following:

(i) A time-limited appointment in the competitive or excepted service;

(ii) A non-permanent appointment in the competitive or excepted service;

(iii) Employment with the government of the District of Columbia (DC) when the candidate was first appointed by the DC government on or after October 1, 1987;

(iv) An appointment as an expert or consultant under 5 U.S.C. 3109 and 5 CFR part 304;

(v) Employment under a provisional appointment designated under 5 CFR 316.403;

(vi) Employment under the Student Career Experience Program under 5 CFR 213.3202(b); or

(vii) Employment as a Senior Executive Service limited term appointee or limited emergency appointee (as defined in 5 U.S.C. 3132(a)(5) and (a)(6), respectively).

* * * * *

(5) An agency may not apply an exception in paragraph (a)(3) of this section if the candidate's civilian employment with the Federal Government during the 90-day period immediately preceding the appointment was in one or more of the following types of positions—

(i) A position to which an individual is appointed by the President, by and with the advice and consent of the Senate;

(ii) A position in the Senior Executive Service as a noncareer appointee (as defined in 5 U.S.C. 3132(a)(7));

(iii) A position excepted from the competitive service by reason of its confidential, policy-determining, policy-making, or policy-advocating character;

(iv) A position to which an individual is appointed by the President without the advice and consent of the Senate;

(v) A position designated as the head of an agency, including an agency headed by a collegial body composed of two or more individual members;

(vi) A position in which the employee is expected to receive an appointment as the head of an agency; or

(vii) A position to which an individual is appointed as a Senior Executive Service limited term appointee or limited emergency appointee (as defined in 5 U.S.C. 3132(a)(5) and (a)(6), respectively) when the appointment must be cleared through the White House Office of Presidential Personnel.

* * * * *

PART 575—RECRUITMENT, RELOCATION, AND RETENTION INCENTIVES; SUPERVISORY DIFFERENTIALS; AND EXTENDED ASSIGNMENT INCENTIVES

3. Revise the authority citation for part 575 to read as follows:

Authority: 5 U.S.C. 1104(a)(2) and 5307; subparts A and B also issued under 5 U.S.C. 5753; subpart C also issued under 5 U.S.C. 5754; subpart D also issued under 5 U.S.C. 5755; subpart E also issued under 5 U.S.C. 5757 and sec. 207 of Public Law 107–273, 116 Stat. 1780.

Subpart A—Recruitment Incentives

4. In § 575.102, revise paragraph (3) in the definition of *newly appointed* to read as follows:

§ 575.102 Definitions.

* * * * *

Newly appointed refers to—* * *

(3) An appointment of an individual in the Federal Government when his or her service in the Federal Government during the 90-day period immediately preceding the appointment was not in a position excluded by section 575.104 and was limited to one or more of the following:

(i) A time-limited appointment in the competitive or excepted service;

(ii) A non-permanent appointment in the competitive or excepted service;

(iii) Employment with the government of the District of Columbia (DC) when the candidate was first appointed by the DC government on or after October 1, 1987;

(iv) An appointment as an expert or consultant under 5 U.S.C. 3109 and 5 CFR part 304;

(v) Employment under a provisional appointment designated under 5 CFR 316.403;

(vi) Employment under the Student Career Experience Program under 5 CFR 213.3202(b); or

(vii) Employment as a Senior Executive Service limited term appointee or limited emergency appointee (as defined in 5 U.S.C. 3132(a)(5) and (a)(6), respectively).

* * * * *

5. In § 575.104—

a. Revise paragraph (d)(1);

b. Remove "or" at the end of paragraph (d)(2);

c. Remove the period at the end of paragraph (d)(3) and add "; or" in its place; and

d. Add paragraph (d)(4).

The revision and addition read as follows:

§ 575.104 Ineligible categories of employees.

* * * * *

(d) * * *

(1) To which an individual is appointed by the President without the advice and consent of the Senate, except a Senior Executive Service position in which the individual serves as a career appointee (as defined in 5 U.S.C. 3132(a)(4));

* * * * *

(4) To which an individual is appointed as a Senior Executive Service limited term appointee or limited emergency appointee (as defined in 5 U.S.C. 3132(a)(5) and (a)(6), respectively) when the appointment must be cleared through the White House Office of Presidential Personnel.

6. In § 575.105, revise paragraph (b) to read as follows:

§ 575.105 Applicability to employees.

* * * * *

(b)(1) An agency may target groups of similar positions (excluding positions covered by § 575.103(a)(2), (a)(3), or (a)(5) or those in similar categories approved by OPM under § 575.103(a)(7)) that have been difficult to fill in the past or that may be difficult to fill in the future and make the required determination to offer a recruitment incentive to newly-appointed employees on a group basis.

(2) An agency must review each decision to target a group of similar positions for the purpose of granting a recruitment incentive at least annually to determine whether the positions are still likely to be difficult to fill. An authorized agency official must certify this determination in writing. If an agency determines the positions are no longer likely to be difficult to fill, the agency may not offer a recruitment incentive to newly-appointed employees in that group on a group basis.

* * * * *

7. In § 575.113, revise paragraph (b) introductory text to read as follows:

§ 575.113 Records and reports.

* * * * *

(b) OPM may require that each agency submit an annual written report to OPM on the use of the recruitment incentive authority within the agency during the previous calendar year. OPM may exempt an agency (or part of an agency) from all or any part of any reporting requirement established under this section if OPM has determined that the recruitment incentive data submitted to OPM's central data systems under 5 CFR 9.2 is accurate and sufficient. Each agency report that is required must include—

* * * * *

§ 575.114 [Removed]

8. Remove § 575.114.

Subpart B—Relocation Incentives

9. In § 575.204—

a. Revise paragraph (d)(1);

b. Remove "or" at the end of paragraph (d)(2);

c. Remove the period at the end of paragraph (d)(3) and add "; or" in its place; and

d. Add paragraph (d)(4).

The revision and addition read as follows:

§ 575.204 Ineligible categories of employees.

* * * * *

(d) * * *

(1) To which an individual is appointed by the President without the advice and consent of the Senate, except a Senior Executive Service position in which the individual serves as a career appointee (as defined in 5 U.S.C. 3132(a)(4));

* * * * *

(4) To which an individual is appointed as a Senior Executive Service limited term appointee or limited emergency appointee (as defined in 5 U.S.C. 3132(a)(5) and (a)(6), respectively) when the appointment must be cleared through the White House Office of Presidential Personnel.

10. In § 575.205, add a sentence at the end of paragraph (b) to read as follows:

§ 575.205 Applicability to employees.

* * * * *

(b) * * * A relocation incentive may be paid only if the employee maintains residency in the new geographic area for the duration of the service agreement.

* * * * *

11. In § 575.211, revise paragraph (b) to read as follows—

§ 575.211 Termination of a service agreement.

* * * * *

(b) An authorized agency official must terminate a relocation incentive service agreement if an employee is demoted or separated for cause (*i.e.,* for

unacceptable performance or conduct), if the employee receives a rating of record (or an official performance appraisal or evaluation under a system not covered by 5 U.S.C. chapter 43 or 5 CFR part 430) of less than "Fully Successful" or equivalent, if the employee fails to maintain residency in the new geographic area for the duration of the service agreement, or if the employee otherwise fails to fulfill the terms of the service agreement.

* * * * *

12. In § 575.213, revise paragraph (b) introductory text to read as follows:

§ 575.213 Records and reports.

* * * * *

(b) OPM may require that each agency submit an annual written report to OPM on the use of the relocation incentive authority within the agency during the previous calendar year. OPM may exempt an agency (or part of an agency) from all or any part of any reporting requirement established under this section if OPM has determined that the relocation incentive data submitted to OPM's central data systems under 5 CFR 9.2 is accurate and sufficient. Each agency report that is required must include—

* * * * *

§ 575.214 [Removed]

13. Remove § 575.214.

Subpart C—Retention Incentives

14. In § 575.304—

a. Revise paragraph (d)(1);

b. Remove "or" at the end of paragraph (d)(2);

c. Remove the period at the end of paragraph (d)(3) and add "; or" in its place; and

d. Add paragraph (d)(4).

The revision and addition read as follows:

§ 575.304 Ineligible categories of employees.

* * * * *

(d) * * *

(1) To which an individual is appointed by the President without the advice and consent of the Senate, except a Senior Executive Service position in which the individual serves as a career appointee (as defined in 5 U.S.C. 3132(a)(4));

* * * * *

(4) To which an individual is appointed as a Senior Executive Service limited term appointee or limited emergency appointee (as defined in 5 U.S.C. 3132(a)(5) and (a)(6), respectively) when the appointment must be cleared through the White House Office of Presidential Personnel.

15. In § 575.305, revise paragraph (c) to read as follows:

§ 575.305 Applicability to employees.

* * * * *

(c) An agency may not include in a group retention incentive authorization an employee covered by § 575.303(a)(2), (a)(3), or (a)(5) or those in similar categories of positions approved by OPM to receive retention incentives under § 575.303(a)(7).

* * * * *

16. In § 575.306, redesignate paragraphs (b)(2) through (8) as paragraphs (b)(3) through (9), respectively, and add a new paragraph (b)(2) to read as follows:

§ 575.306 Authorizing a retention incentive.

* * * * *

(b) * * *

(2) The quality and availability of the potential sources of employees that are identified in the agency's succession plan, who possess the competencies required for the position, and who, with minimal training, cost, and disruption of service to the public, could perform the full range of duties and responsibilities of the employee's position at the level performed by the employee;

* * * * *

17. In § 575.311, redesignate paragraphs (a)(1) and ((2) as paragraphs (a)(2) and (3), respectively, and add a new paragraph (a)(1) to read as follows:

§ 575.311 Continuation, reduction, and termination of retention incentives.

(a)(1) For each retention incentive that is subject to a service agreement, an authorized agency official must review the determination to pay a retention incentive at least annually to determine whether the original determination still applies or whether payment is still warranted as provided in paragraph (a)(2) of this section, and must certify this determination in writing.

* * * * *

18. In § 575.313, revise paragraph (b) introductory text to read as follows:

§ 575.313 Records and reports.

* * * * *

(b) OPM may require that each agency submit an annual written report to OPM on the use of the retention incentive authority within the agency during the previous calendar year. OPM may exempt an agency (or part of an agency) from all or any part of any reporting requirement established under this section if OPM has determined that the retention incentive data submitted to OPM's central data systems under 5 CFR 9.2 is accurate and sufficient. Each agency report that is required must include—

* * * * *

§ 575.314 [Removed]

19. Remove § 575.314.

§ 575.315 [Redesignated as § 575.314]

20. Redesignate § 575.315 as § 575.314.

§ 575.314 [Amended]

21. In newly redesignated § 575.314:

a. Redesignate paragraph (i)(1) as paragraph (i) introductory text;

b. Remove paragraph (i)(2); and

c. Redesignate paragraphs (i)(1)(i) through (i)(1)(v) as paragraphs (i)(1) through (i)(5),

[FR Doc. 2011–111 Filed 1–6–11; 8:45 am]

BILLING CODE 6325–39–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 40

[NRC–2011–0003]

RIN 3150–AH15

Implementation Guidance for Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions; Draft Guidance Document for Comment

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability of draft guidance for public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to require that the initial distribution of source material to exempt persons or general licensees be explicitly authorized by a specific license. The proposed rule would also modify the existing possession and use requirements of the general license for small quantities of source material and revise, clarify, or delete certain source material exemptions from licensing. The NRC has prepared draft guidance to address implementation of the proposed regulations. This notice is announcing the availability of the draft implementation guidance document for public comment.

DATES: Submit comments by March 8, 2011. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID NRC–2011–0003 in the subject line of

your comments. For instructions on submitting comments and accessing documents related to this action, see "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods.

Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0003. Address questions about NRC dockets to Carol Gallagher, telephone: 301–492–3668; e-mail: *Carol.Gallagher@nrc.gov.*

Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Fax comments to: RADB at 301–492–3446.

FOR FURTHER INFORMATION CONTACT: Gary Comfort, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–8106, e-mail: *Gary.Comfort@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal Rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

NRC's Public Document Room (PDR): The public may examine and have copied for a fee publicly available documents at the NRC's PDR, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

NRC's Agencywide Documents Access and Management System (ADAMS): Publicly available documents created or received at the NRC are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail to *PDR.Resource@nrc.gov.* The draft Part 40 implementation guidance is available electronically under ADAMS Accession Number ML103160241.

Federal Rulemaking Web site: Public comments and supporting materials related to the implementation guidance, including the draft implementation guidance, can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0003. Documents related to the proposed rule can be found by searching on Docket ID NRC–2009–0084.

Discussion

The NRC published a proposed rule (75 FR 43425; July 26, 2010) that would amend its regulations in part 40 of Title 10 of the Code of Federal Regulations (10 CFR) to require that the initial distribution of source material to exempt persons or general licensees be explicitly authorized by a specific license, which would include new reporting requirements. This proposed rule would affect manufacturers and distributors of certain products and materials containing source material and certain persons using source material under general license and under exemptions from licensing. The public comment period runs through February 15, 2011.

In conjunction with the proposed rule, the NRC has developed draft implementation guidance. The draft implementation document provides guidance to a licensee or applicant for implementation of proposed 10 CFR Part 40, "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions." It is intended for use by applicants, licensees, Agreement States, and NRC staff. The document describes methods acceptable to the NRC staff for implementing proposed 10 CFR part 40. The approaches and methods described in the document are provided for information only. Methods and solutions different from those described in the document are acceptable if they meet the requirements in proposed 10 CFR part 40. The guidance is provided in the form of questions and answers on the provisions of the proposed rule. The draft implementation guidance document for proposed 10 CFR part 40 is available electronically under ADAMS Accession Number ML103160241, and can also be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0003.

At this time, the NRC is announcing the availability for public comment of "Implementation Guidance for 10 CFR Part 40 Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions." The document provides guidance on implementing the provisions of proposed 10 CFR part 40, "Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions."

Dated at Rockville, Maryland, this 28th day of December 2010.

For the Nuclear Regulatory Commission.

James Luehman,

Deputy Director, Licensing and Inspection Directorate, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs.

[FR Doc. 2011–107 Filed 1–6–11; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–131947–10]

RIN 1545–BJ71

Property Traded on an Established Market

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to determining when property is traded on an established market (that is, publicly traded) for purposes of determining the issue price of a debt instrument. The regulations amend the current regulations to clarify the circumstances that cause property to be publicly traded. The regulations provide needed guidance to issuers and holders of debt instruments. This document also provides a notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by March 8, 2011. Outlines of topics to be discussed at the public hearing scheduled for April 13,

2011, at 10 a.m. must be received by March 4, 2011.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–131947–10), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–131947–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–131947–10).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, William E. Blanchard at (202) 622–3950; concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, *Oluwafunmilayo.P.Taylor@irscounsel.treas.gov,* at (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The issue price of a debt instrument is determined under section 1273(b) of the Internal Revenue Code or, in the case of certain debt instruments issued for property, under section 1274. Section 1273(b)(3) generally provides that in the case of a debt instrument that is issued for property and that is part of an issue some or all of which is traded on an established securities market (often referred to as "publicly traded"), the issue price of the debt instrument is the fair market value of the debt instrument. Similarly, if the debt instrument is issued for stock or securities (or other property) that are publicly traded, the issue price of the debt instrument is the fair market value of the property. Section 1.1273–2 of the Income Tax Regulations (the "current regulations") also applies to determine the issue price of a debt instrument that is publicly traded or is issued for publicly traded property. Under § 1.1273–2(c)(1), the term *property* means a debt instrument, stock, security, contract, commodity, or nonfunctional currency. Section 1.1273–2(f) defines when property is traded on an established market (that is, publicly traded) for purposes of section 1273(b)(3) and § 1.1273–2.

In general, under § 1.1273–2(f) of the current regulations, a debt instrument is traded on an established market if either the debt instrument or the property for which the debt instrument is exchanged is described in § 1.1273–2(f)(2) through (f)(5) in the time period 30 days before or after the exchange. Property is described in § 1.1273–2(f)(2) if it is listed on a specified exchange. Property is described in § 1.1273–2(f)(3) if it is of a kind that is traded on a contract market designated by the Commodities Futures Trading Commission or an interbank market. Property is described in § 1.1273–2(f)(4) if it appears on a system of general circulation that disseminates price quotations or recent trading prices. Property is described in § 1.1273–2(f)(5) if price quotations are readily available from dealers, brokers or traders, subject to certain exceptions.

The issue price of a debt instrument has important income tax consequences. As an initial matter, the difference between the issue price of a debt instrument and its stated redemption price at maturity measures whether there is any original issue discount associated with the instrument. A debt-for-debt exchange (including a significant modification of existing debt) in the context of a work-out may result in a reduced issue price for the new debt, which generally would produce cancellation of indebtedness income for the issuer, a loss to the holder whose basis is greater than the issue price of the new debt, and original issue discount that generally must be accounted for by both the issuer and the holder of the new debt. These consequences, exacerbated by recent turmoil in the debt markets, have focused attention on the definition of when property is traded on an established market for purposes of § 1.1273–2(f).

Commenters have criticized the definition of an established market in § 1.1273–2(f) of the current regulations. They argue that comparatively little debt is listed on an exchange described in § 1.1273–2(f)(2), and that even debt that is listed rarely trades on the exchange. They point out that the list of foreign exchanges in § 1.1273–2(f)(2)(iii) is outdated. Commenters also struggle to interpret the meaning of an interbank market in § 1.1273–2(f)(3).

Even more troublesome for commenters is the question of what constitutes a quotation medium for purposes of § 1.1273–2(f)(4) of the current regulations. Debt instruments typically trade in various ways in the current markets, but the vast majority of debt instruments are purchased or sold over-the-counter for a price negotiated between a financial entity (such as a securities dealer or broker) and a customer. A dealer or broker may quote a firm price, sometimes referred to as a "firm" or "executable" quote, entitling a customer to purchase or sell at that price, subject to volume limits or other specified restrictions. Alternatively, a dealer, broker or listing service may quote a price that indicates a willingness to purchase and/or sell a specified debt instrument, again subject to volume limits or other limitations, but not necessarily at the quoted price. This is sometimes referred to as a "soft" or an "indicative" quote. The decision to send a price quote to a customer (or customers) may be initiated by a dealer or broker, or a customer may request a price quote from one or more dealers or brokers. Additionally, a service provider may provide subscribers with valuations based on data collected from contributors that may reflect actual sales, price quotes, or any other information it deems relevant to the value of the debt instrument in question. Commenters struggled to apply the description of a quotation medium in § 1.1273–2(f)(4) to this informal marketplace, which has evolved considerably since the regulations were originally promulgated in 1994.

Finally, commenters pointed out that the general rule in § 1.1273–2(f)(5) of the current regulations, which treats a debt instrument as publicly traded if price quotations are readily available from dealers, brokers or traders could cause almost every debt instrument to be within this definition but for the safe harbors in § 1.1273–2(f)(5)(ii).

Explanation of Provisions

As a general matter, the Treasury Department and the IRS believe that the "traded on an established market" standard established by section 1273(b)(3) is intended to be interpreted broadly. When section 1275(a)(4) was repealed by section 11325(a)(2) of the Revenue Reconciliation Act of 1990, Public Law 101–508, 104 Stat. 1388, 1388–466 (1990), issue price was required to be determined under section 1273 and section 1274 even in a debt-for-debt exchange that qualified as a corporate reorganization. As the depth of trading and the transparency of the markets that trade debt instruments has improved, the earlier concerns that trading prices may not reflect the fair market value of a debt instrument have diminished. Thus, to the extent accurate pricing information exists, whether it derives from executed sales, reliable price quotations, or valuation estimates that are based on some combination of sales and quotes, the Treasury Department and the IRS believe that that information should be the basis for the issue price determined under section 1273(b)(3).

To address concerns with the current regulations, the proposed regulations

simplify and clarify the determination of when property is traded on an established market. The proposed regulations identify four ways for property to be traded on an established market. In each case, the time period for determining whether the property is publicly traded is the 31-day period ending 15 days after the issue date of the debt instrument.

First, property that is listed on an exchange continues to be publicly traded property under § 1.1273–2(f)(2) of the proposed regulations. Although relatively few debt instruments are listed or traded on an exchange, the regulations may still apply to other property that is listed, such as stock for which a debt instrument is issued in a debt-for-stock exchange. The proposed regulations, however, delete the reference to an interdealer quotation system that is sponsored by a national securities association registered under section 15A of the Securities Exchange Act of 1934 because none exist or are contemplated. Rather than list foreign exchanges, the proposed regulations specify that a foreign securities exchange that is officially recognized, sanctioned, regulated or supervised by a governmental authority of the foreign country in which the market is located is an exchange that causes property to be publicly traded.

Second, § 1.1273–2(f)(3) of the proposed regulations treats property as publicly traded when a sales price for the property is reasonably available. Market participants have access to information about the securities markets from a variety of sources, which are constantly changing and evolving. If information about the sales price of a debt instrument (or information sufficient to calculate the sales price) appears in a medium that is made available to persons that regularly purchase or sell debt instruments, or persons that broker purchases or sales of debt instruments, the sales price will be considered reasonably available. For example, in the case of a debt instrument, a sale that is reported electronically at any time in the 31-day time period, such as in the Trade Reporting and Compliance Engine (''TRACE'') database maintained by the Financial Industry Regulatory Authority, would cause the instrument to be publicly traded, as would other pricing services and trading platforms that report prices of executed sales on a general basis or to subscribers.

Third, property is considered to be traded on an established market if a firm price quote to buy or sell the property is available. A firm, or executable, price quote may be labeled as such, or a price quote may function as a firm quote as a matter of law or industry practice. In either case, § 1.1273–2(f)(4) of the proposed regulations treats property with a firm quote as publicly traded.

Finally, a price quote (other than a firm quote) that is provided by a dealer, a broker, or a pricing service (an indicative quote) will cause property to be publicly traded under § 1.1273–2(f)(5) of the proposed regulations.

The proposed regulations provide that the fair market value of property described in § 1.1273–2(f) will be presumed to be equal to its trading price, sales price, or quoted price, whichever is applicable. However, if there is more than one price or quote, a taxpayer is permitted to reconcile competing prices or quotes in a reasonable manner. In the case of an indicative quote, if a taxpayer determines that the quoted price or prices misrepresents the fair market value of the property by a material amount, § 1.1273–2(f)(6)(ii) of the proposed regulations permits the taxpayer to use any method that provides a reasonable basis to determine the fair market value of the property, provided the taxpayer can establish that the method chosen more accurately reflects the value of the property than the extant quote or quotes for the property.

In response to commenters, the proposed regulations also contain guidance in areas ancillary to publicly traded debt, such as proposed regulations clarifying and revising the rules to determine when an issue of debt instruments is eligible to be part of a qualified reopening under § 1.1275–2(k) and proposed regulations clarifying the treatment of a debt instrument issued in a debt-for-debt exchange under the potentially abusive rules in section 1274(b)(3). In addition, in response to commenters, the proposed regulations include a business day convention to determine if certain stated interest payments affect whether the payments are qualified stated interest.

Proposed Effective Date

The regulations, as proposed, apply to debt instruments that have an issue date on or after the publication date of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for April 13, 2011, beginning at 10 a.m. in the Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. All visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit electronic or written comments and an outline of the topics to be discussed and the time to be devoted to each topic by March 4, 2011. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

These regulations were drafted by personnel in the Office of Associate Chief Counsel (Financial Institutions and Products) and the Treasury Department.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.1273–1 is amended by adding a new paragraph (c)(6) to read as follows:

§ 1.1273–1 Definition of OID.

* * * * *

(c) * * *

(6) *Business day convention*—(i) *Rule.* For purposes of this paragraph (c), if a scheduled payment date for stated interest falls on a Saturday, Sunday, or Federal holiday (within the meaning of 5 U.S.C. 6103) but, under the terms of the debt instrument, the stated interest is payable on the first business day that immediately follows the scheduled payment date, the stated interest is treated as payable on the scheduled payment date, provided no additional interest is payable as a result of the deferral.

(ii) *Effective/applicability date.* Paragraph (c)(6)(i) of this section applies to debt instruments that are issued on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**. A taxpayer, however, may rely on paragraph (c)(6)(i) of this section for debt instruments issued before that date.

* * * * *

Par. 3. Section 1.1273–2 is amended by revising paragraph (f) to read as follows:

§ 1.1273–2 Determination of issue price and issue date.

* * * * *

(f) *Traded on an established market (publicly traded)*—(1) *In general.* Except as provided in paragraph (f)(7) or (f)(8) of this section, property (including a debt instrument described in paragraph (b)(1) of this section) is traded on an established market for purposes of this section if, at any time during the 31-day period ending 15 days after the issue date—

(i) The property is listed on an exchange described in paragraph (f)(2) of this section;

(ii) There is a sales price for the property as described in paragraph (f)(3) of this section;

(iii) There are one or more firm quotes for the property as described in paragraph (f)(4) of this section; or

(iv) There are one or more indicative quotes for the property as described in paragraph (f)(5) of this section.

(2) *Exchange listed property.* Property is listed on an exchange for purposes of this paragraph (f)(2) if it is listed on—

(i) A national securities exchange registered under section 6 of the Securities Exchange Act of 1934 (15 U.S.C. 78f);

(ii) A board of trade designated as a contract market by the Commodities Futures Trading Commission;

(iii) A foreign securities exchange that is officially recognized, sanctioned, regulated or supervised by a governmental authority of the foreign country in which the market is located; or

(iv) Any other exchange, board of trade, or other market which the Commissioner identifies in guidance published in the Internal Revenue Bulletin (see § 601.601(d)(2)(ii)) as an exchange for purposes of this paragraph (f)(2).

(3) *Sales price*—(i) *In general.* A sales price exists if the price for an executed purchase or sale of the property is reasonably available.

(ii) *Pricing information for a debt instrument.* For purposes of paragraph (f)(3)(i) of this section, the price of a debt instrument is considered reasonably available if the sales price (or information sufficient to calculate the sales price) appears in a medium that is made available to persons that regularly purchase or sell debt instruments (including a price provided only to certain customers or to subscribers), or persons that broker purchases or sales of debt instruments.

(4) *Firm quote.* A firm quote is considered to exist when a price quote is available from at least one broker, dealer, or pricing service (including a price provided only to certain customers or to subscribers) for property and the quoted price is substantially the same as the price for which the property could be purchased or sold. The identity of the person providing the quote must be reasonably ascertainable for a quote to be considered a firm quote for purposes of this paragraph (f)(4). A quote will be considered a firm quote if market participants typically purchase or sell, as the case may be, at the quoted price, even if the party providing the quote is not legally obligated to do so.

(5) *Indicative quote.* An indicative quote is considered to exist when a price quote is available from at least one broker, dealer, or pricing service (including a price provided only to certain customers or to subscribers) for property and the price quote is not a firm quote described in paragraph (f)(4) of this section.

(6) *Presumption that price or quote is equal to fair market value*—(i) *In general.* The fair market value of property described in this section will be presumed to be equal to its trading price on an exchange described in paragraph (f)(2) of this section, or its sales price or quoted price determined under paragraphs (f)(3) through (f)(5) of this section. If there is more than one trading price under paragraph (f)(2) of this section, sales price under paragraph (f)(3) of this section, or quoted price under paragraph (f)(4) or (f)(5) of this section, a taxpayer may use any reasonable method, consistently applied, to determine the price.

(ii) *Special rule for property for which there is only an indicative quote.* If property is described only in paragraph (f)(5) of this section, and the taxpayer determines that the quote (or an average of the quotes) materially misrepresents the fair market value of the property, the taxpayer can use any method that provides a reasonable basis to determine the fair market value of the property. A taxpayer must establish that the method chosen more accurately reflects the value of the property than the quote or quotes for the property to use the method provided in this paragraph (f)(6)(ii). For an equity or debt instrument, a volume discount or control premium will not be considered to create a material misrepresentation of value for purposes of this paragraph (f)(6).

(7) *Exception for property for which there is de minimis trading*—(i) *In general.* Notwithstanding any other provision in this section, property will not be treated as traded on an established market if there is no more than de minimis trading of the property.

(ii) *Definition of de minimis trading for debt instruments.* For purposes of paragraph (f)(7)(i) of this section, a debt instrument will be treated as traded in de minimis quantities only if—

(A) Each trade of such debt instrument during the 31-day period ending 15 days after the issue date is for quantities of US$1 million or less (or, for debt denominated in a currency other than the U.S. dollar, the equivalent amount in the currency in which the debt is denominated); and

(B) The aggregate amount of all such trades does not exceed US$5 million (or, for debt denominated in a currency other than the U.S. dollar, the equivalent amount in the currency in which the debt is denominated).

(8) *Exception for small debt issues.* Notwithstanding any other provision in this section, a debt instrument will not be treated as traded on an established market if the original stated principal amount of the issue that includes the debt instrument does not exceed US$50 million (or, for debt denominated in a currency other than the U.S. dollar, the equivalent amount in the currency in which the debt is denominated).

(9) *Anti-abuse rules*—(i) *Effect of certain temporary restrictions on trading.* If there is any temporary restriction on trading, a purpose of which is to avoid the characterization of the property as one that is traded on an established market for Federal income tax purposes, then the property is treated as traded on an established market. For purposes of the preceding sentence, a temporary restriction on trading need not be imposed by the issuer.

(ii) *Artificial pricing information.* If a principal purpose for the existence of any sale or price quotation is to materially misrepresent the value of property, that sale or price quotation may be disregarded.

(10) *Convertible debt instruments.* A debt instrument is not treated as traded on an established market solely because the debt instrument is convertible into property that is so traded.

(11) *Effective/applicability date.* Paragraph (f) of this section applies to a debt instrument issued on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

Par. 4. Section 1.1274–3 is amended by adding a new paragraph (b)(4) to read as follows:

§ 1.1274–3 Potentially abusive situations defined.

* * * * *

(b) * * *

(4) *Debt-for-debt exchange*—(i) *Rule.* A debt instrument issued in a debt-for-debt exchange, including a deemed exchange under § 1.1001–3, will not be treated as the subject of a recent sales transaction for purposes of section 1274(b)(3)(B)(ii)(I) even if the debt instrument exchanged for the newly issued debt instrument was recently acquired prior to the exchange. Therefore, the issue price of the debt instrument will not be determined under section 1274(b)(3). However, if the debt instrument or the property for which the debt instrument is issued is publicly traded within the meaning of § 1.1273–2(f), the rules of § 1.1273–2 will apply to determine the issue price of the debt instrument.

(ii) *Effective/applicability date.* Paragraph (b)(4)(i) of this section applies to a debt instrument issued on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

Par. 5. Section 1.1275–2 is amended by revising paragraphs (k)(3)(ii)(A), (k)(3)(iii)(A) and (k)(5) and adding a new paragraph (k)(3)(v) to read as follows:

§ 1.1275–2 Special rules relating to debt instruments.

* * * * *

(k) * * *

(3) * * *

(ii) * * *

(A) The original debt instruments are publicly traded (within the meaning of § 1.1273–2(f)) as of the reopening date of the additional debt instruments;

* * * * *

(iii) * * *

(A) The original debt instruments are publicly traded (within the meaning of § 1.1273–2(f)) as of the reopening date of the additional debt instruments;

* * * * *

(v) *Non-publicly traded debt issued for cash.* Notwithstanding paragraphs (k)(3)(ii)(A) and (k)(3)(iii)(A) of this section, a qualified reopening includes a reopening of original debt instruments if the additional debt instruments are issued for cash to persons unrelated to the issuer (as determined under section 267(b) or 707(b)) for an arm's length price and the other requirements in paragraph (k)(3)(ii) or (k)(3)(iii) of this section are satisfied, whichever is applicable. For purposes of paragraph (k)(3)(ii)(C) of this section, the yield test is satisfied if, on the reopening date of the additional debt instruments, the yield of the additional debt instruments (based on their cash purchase price) is not more than 110 percent of the yield of the original debt instruments on their issue date (or, if the original debt instruments were issued with no more than a de minimis amount of OID, the coupon rate).

* * * * *

(5) *Effective/applicability dates*—(i) Except as provided in paragraph (k)(5)(ii) of this section, this paragraph (k) applies to debt instruments that are part of a reopening where the reopening date is on or after March 13, 2001.

(ii) Paragraph (k)(3)(v) of this section applies to debt instruments that are part of a reopening if the reopening date is on or after the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2011–83 Filed 1–6–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 31

[REG–146097–09]

RIN 1545–BJ01

Guidance on Reporting Interest Paid to Nonresident Aliens

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; notice of public hearing; and withdrawal of previously proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance on the reporting requirements for interest on deposits maintained at U.S. offices of certain financial institutions and paid to nonresident alien individuals. These proposed regulations affect persons making payments of interest with respect to such deposits. This document also provides a notice of public hearing on these proposed regulations and withdraws the notice of proposed rulemaking published on August 2, 2002 (67 FR 50386).

DATES: Written or electronic comments must be received by April 7, 2011. Outlines of topics to be discussed at the public hearing scheduled for April 28, 2011, at 10 a.m. must be received by April 8, 2011. The proposed rule published on August 2, 2002 is withdrawn as of January 7, 2011.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–146097–09), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–146097–09), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–146097–09). The public hearing will be held in auditorium of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Kathryn Holman, (202) 622–3840; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, *Richard.A.Hurst@irscounsel.treas.gov,* (202) 622–7180 (not toll free numbers).

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Office for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by March 8, 2011. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collections of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance and purchase of service to provide information.

The collection of information in these proposed regulations is in § 1.6049–4(b)(5)(i) and § 1.6049–6(e)(4)(i) and (ii). This information is required to determine if taxpayers have properly reported amounts received as income. The collection of information is mandatory. The likely respondents are businesses and other for-profit institutions.

Estimated total annual reporting burden: 500 hours.

The estimated annual burden per respondent: 15 minutes.

Estimated number of respondents: 2,000.

Estimated annual frequency of responses: Annually.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential as required by 26 U.S.C. 6103.

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

On January 17, 2001, the IRS and Treasury Department published a notice of proposed rulemaking (REG 126100–00) in the **Federal Register** (66 FR 3925, corrected by 66 FR 15820 and 66 FR 16019) under Section 6049 (the 2001 proposed regulations), which would provide that U.S. bank deposit interest paid to any nonresident alien individual must be reported annually to the IRS. On August 2, 2002, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–133254–02) in the **Federal Register** (67 FR 50386) which withdrew these regulations and proposed narrower regulations (the 2002 regulations) that would require reporting only on interest payments to nonresident alien individuals that are residents of certain designated countries or, at the option of the payor, on interest payments to all nonresident alien recipients of bank deposit interest. Under the 2002 regulations currently in effect, reporting of U.S. bank deposit interest is required only if the interest is paid to a U.S. person or a nonresident alien individual who is a resident of Canada. These proposed regulations withdraw the 2002 regulations and provide new proposed regulations that extend the information reporting requirement to include bank deposit interest paid to nonresident alien individuals who are residents of any foreign country.

This extension is appropriate for several reasons. First, since the 2002 proposed regulations were released, there is a growing global consensus regarding the importance of cooperative information exchange for tax purposes that has developed. Significant agreements have been reached on international standards for the exchange of information, including, for example, the understanding that information exchange will not be limited by bank secrecy or the absence of a domestic tax interest. Second, requiring routine reporting to the IRS of all U.S. bank deposit interest paid to any nonresident alien individual will further strengthen the United States exchange of information program, consistent with adequate provisions for reciprocity, usability, and confidentiality in respect of this information. Finally, this extension will help to improve voluntary compliance by U.S. taxpayers by making it more difficult to avoid the U.S. information reporting system (such as through false claims of foreign status).

In addition to requiring reporting of U.S. bank deposit interest paid to any nonresident alien individual, the proposed regulations also make the following minor changes and clarifications. Section 1.6049–6 provides that a copy of Form 1042–S, "Foreign Person's U.S. Source Income Subject to Withholding", must be furnished to the recipient for interest paid on deposits maintained at a bank's office within the United States. Section 1.6049–6(e)(4) has been revised to clarify that the payor or middleman can satisfy this requirement by furnishing a copy of Form 1042–S either in person or to the last known address of the recipient.

Proposed Effective Date

These regulations are proposed to apply to payments made after December 31 of the year in which they are published as final regulations in the **Federal Register.**

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation.

These regulations impose a collection of information on small entities, and the Regulatory Flexibility Act (5 U.S.C. chapter 6) applies. This rule regulates commercial banks, savings institutions, credit unions, and securities brokerages. The Small Business Administration (SBA) has established size standards for types of economic activities which are classified based on the North American Industry Classification Codes (NAICS). The regulations specifying size standards are set forth in Title 13, Code of Federal Regulations, part 121 (13 CFR part 121), Small Business Size Regulations. The NAICS Code for small commercial banks, savings institutions, credit unions, and securities brokerages

is specified at 13 CFR 121.201. Pursuant to subsectors 522110, 522120, and 522130 of NAICS 2007, a small commercial bank, savings institution, or credit union is one with $175 million or less in assets. Pursuant to subsector 523120 of NAICS 2007, a small securities brokerage is one with receipts of less than $7 million. Because this rule will affect all institutions that maintain accounts for nonresident alien individuals, this rule may affect a substantial number of small entities.

The U.S. Census Bureau American FactFinder provides data based on the 2007 Economic Census released November 24, 2009 including the number of establishments and the annual revenue of the establishments within each NAICS Code. According to this data, for Sector 52: ECO752I1: Finance and Insurance Industry Series, there were 94,192 commercial banking establishments with revenue of approximately $609,748,098,000, 16,098 savings institutions with revenue of approximately $91,626,050,000, 17,984 credit unions with revenue of approximately $55,521,199,000, and 30,989 NAICS Code securities brokerages with revenue of approximately $167,337,807,000. It is estimated that approximately 25,000 commercial banks, 4,000 savings banks, and 4,000 credit unions with less than $175,000,000 in assets, and 15,000 securities brokerages with receipts of less than $7,000,000 that would be classified as small businesses.

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. Section 605, the Chief Counsel certifies that this rule will not have a significant economic impact on a substantial number of small entities. This conclusion is based on all of the following. The depository accounts, the interest on which is subject to reporting under these regulations, tend to be with larger financial institutions operating in the United States, and therefore the number of small entities that will be required to undertake this collection of information is expected to be limited. Banks are already required to gather the underlying information from nonresident aliens on Form W–8, so there will be no change in the collection of information. Currently under the 2002 regulations, banks, including small financial institutions, are required to report this information to the IRS with respect to Canadian account holders. This rule would simply extend the reporting requirement to all nonresident aliens. The reporting required by this rule would be done on Form 1042 and Form 1042–S. This rule also requires that institutions prepare and deliver a statement to nonresident alien individuals to the effect that the information on the 1042 form is being furnished to the IRS and may be furnished to the government of the foreign country where the recipient resides. The amount of time required to complete the Form 1042 and Form 1042–S is brief, and the statement that is required to be collected is brief.

The IRS requests information regarding the economic impact of this rule on small commercial banks, savings institutions, credit unions, and small securities brokerages engaged in business involving payment of bank deposit interest to a nonresident alien. The IRS invites specific comments on the economic impact of compliance from members of the public who believe there will be a significant economic impact on small businesses that are regulated by this rule. Pursuant to section 7805(f) of the Internal Revenue Code, this regulation has been submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small businesses.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for April 28, 2011, beginning at 10 a.m. in the auditorium of the Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit electronic or written comments and an outline of the topics to be discussed and the time to be devoted to each topic (signed original and eight (8) copies) by April 8, 2011. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of the regulations is Kathryn Holman, Office of Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social Security, Unemployment compensation.

Withdrawal of Proposed Amendments

Accordingly, under the authority of 26 U.S.C. 7805, the proposed amendment to 26 CFR parts 1 and 31 that was published in the **Federal Register** on Friday, August 2, 2002 (67 FR 50386) is withdrawn.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 31 are proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. In § 1.6049–4, paragraph (b)(5) is revised to read as follows:

§ 1.6049–4 Return of information as to interest paid and original issue discount includible in gross income after December 31, 1982.

* * * * *

(b) * * *

(5) *Interest payments to nonresident alien individuals*—(i) *General rule.* In the case of interest aggregating $10 or more paid to a nonresident alien individual (as defined in section 7701(b)(1)(B)) that is reportable under § 1.6049–8(a), the payor shall make an information return on Form 1042–S, "Foreign Person's U.S. Source Income Subject to Withholding", for the calendar year in which the interest is paid. The payor or middleman shall prepare and file Form 1042–S at the

time and in the manner prescribed by section 1461 and the regulations under that section and by the form and its accompanying instructions. See §§ 1.1461–1(b) (rules regarding the preparation of a Form 1042) and 1.6049–6(e)(4) (rules for furnishing a copy of the Form 1042–S to the payee). To determine whether an information return is required for original issue discount, see §§ 1.6049–5(f) and 1.6049–8(a). The Commissioner may by ruling or other administrative pronouncement prescribe rules pursuant to a treaty or executive agreement for uniform formatting, standards for sharing information, and for usability, reciprocity, and confidentiality of taxpayer information.

(ii) *Effective/applicability date.* Paragraph (b)(5)(i) of this section shall be effective for payments made after December 31 of the year in which the final regulations are published in the **Federal Register**. (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see paragraph (b)(5) of this section as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

* * * * *

Par. 3. Section 1.6049–5 is amended as follows:

1. In paragraph (b)(12) the last sentence is revised.

2. In paragraph (f) the last sentence is revised.

The revisions read as follows:

§ 1.6049–5 Interest and original issue discount subject to reporting after December 31, 1982.

* * * * *

(b) * * *

(12) * * * This paragraph (b)(12) does not apply to interest paid after December 31 of the year in which the final regulations are published in the **Federal Register** to a nonresident alien individual as provided in § 1.6049–8.

* * * * *

(f) * * * Original issue discount on an obligation (including an obligation with a maturity of not more than 6 months from the date of original issue) held by a nonresident alien individual or foreign corporation is interest described in paragraph (b)(1)(vi)(A) or (B) of this section and, therefore is not interest subject to reporting under section 6049 unless it is described in § 1.6049–8(a) (relating to bank deposit interest paid after December 31 of the year in which the final regulations are published in the **Federal Register** to a nonresident alien individual).

* * * * *

Par. 4. Section 1.6049–6 is amended as follows:

1. Paragraph (e)(4) is revised.

2. In paragraph (e)(5), the first sentence is revised and a new sentence is added at the end of the paragraph.

The additions and revisions read as follows:

§ 1.6049–6 Statements to recipients of interest payments and holders of obligations for attributed original issue discount.

* * * * *

(e) * * *

(4) *Special rule for amounts described in § 1.6049–8(a).* In the case of amounts described in § 1.6049–8(a) (relating to payments of deposit interest to nonresident alien individuals) paid after December 31 of the year in which the final regulations are published in the **Federal Register,** any person who makes a Form 1042–S, "Foreign Person's U.S. Source Income Subject to Withholding", under section 6049(a) and § 1.6049–4(b)(5) shall furnish a statement to the recipient either in person or by first class mail to the recipient's last known address. The statement shall include a copy of the Form 1042–S required to be prepared pursuant to § 1.6049–4(b)(5) and a statement to the effect that the information on the form is being furnished to the United States Internal Revenue Service and may be furnished to the government of the foreign country where the recipient resides.

(5) *Effective/applicability date.* Paragraph (e)(4) of this section applies to payee statements reporting payments of deposit interest to nonresident alien individuals paid after December 31 of the year in which the final regulations are published in the **Federal Register**. * * * (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see paragraph (e)(4) of this section as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

Par. 5. In § 1.6049–8 the section heading and paragraph (a) are revised to read as follows:

§ 1.6049–8 Interest and original issue discount paid to nonresidents.

(a) *Interest subject to reporting requirement.* For purposes of §§ 1.6049–4, 1.6049–6, and this section and except as provided in paragraph (b) of this section, the term interest means interest paid to a nonresident alien individual after December 31 of the year in which the final regulations are published in the **Federal Register**, where the interest is described in section 871(i)(2)(A) with respect to a deposit maintained at an office within the United States. For purposes of the regulations under section 6049, a nonresident alien individual is a person described in section 7701(b)(1)(B). The payor or middleman may rely upon a valid Form W–8BEN, "Beneficial Owners Certificate of Foreign Status for U.S. Tax Withholding" to determine whether the payment is made to a nonresident alien individual. Generally, amounts described in this paragraph (a) are not subject to backup withholding under section 3406. See § 31.3406(g)–1(d) of this chapter. However, if the payor or middleman does not have either a valid Form W–8BEN or valid Form W–9, "Request for Taxpayer Identification Number and Certification", the payor or middleman must report the payment as made to a U.S. non-exempt recipient if it must so treat the payee under the presumption rules of § 1.6049–5(d)(2) and § 1.1441–1(b)(3)(iii) and must also backup withhold under section 3406. (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see paragraph (a) of this section as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

* * * * *

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT THE SOURCE

Par. 6. The authority citation for part 31 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 7. In § 31.3406(g)–1, paragraph (d) is revised to read as follows:

§ 31.3406(g)–1 Exceptions for payments to certain payees and certain other payments.

* * * * *

(d) *Reportable payments made to nonresident alien individuals.* A payment of interest that is reported on Form 1042–S, "Foreign Person's U.S. Source Income Subject to Withholding," as paid to a nonresident alien individual under § 1.6049–8(a) of this chapter is not subject to withholding under section 3406. (For interest paid to a Canadian nonresident alien individual on or before December 31 of the year in which final regulations are published in the **Federal Register**, see paragraph (d) of this section as in effect and contained in 26 CFR part 1 revised April 1, 2000.)

* * * * *

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2011–82 Filed 1–6–11; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 52, 72, 78, and 97

[EPA–HQ–OAR–2009–0491; FRL–9249–6]

RIN 2060–AP50

Notice of Data Availability for Federal Implementation Plans To Reduce Interstate Transport of Fine Particulate Matter and Ozone: Request for Comment on Alternative Allocations, Calculation of Assurance Provision Allowance Surrender Requirements, New-Unit Allocations in Indian Country, and Allocations by States

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability (NODA) for the proposed Transport Rule and request for comment.

SUMMARY: EPA has supplemented the Transport Rule docket with additional information relevant to the rulemaking, including unit-level SO_2 Group 1 and Group 2, NO_X annual, and NO_X ozone season allowances for existing units calculated using two alternative methodologies and data supporting those calculations. This NODA requests public comment on these two alternative allocation methodologies for existing units, on the unit-level allocations calculated using those alternative methodologies, on the data supporting the calculations, and on any resulting implications for the proposed assurance provisions. This NODA also requests comment on information about: An alternative approach to calculation of assurance provision allowance surrender requirements; allocations for new units locating in Indian country in the proposed Transport Rule region in the future; and provisions for states to submit State Implementation Plans providing for State allocation of allowances in the proposed Transport Rule trading programs.

DATES: Comments on this NODA must be received on or before February 7, 2011.

Please refer to **SUPPLEMENTARY INFORMATION** for additional information on submitting comments.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2009–0491, by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments. Attention Docket ID No. EPA–HQ–OAR–2009–0491.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2009–0491.
- *Mail:* EPA Docket Center, EPA West (Air Docket), Attention Docket ID No. EPA–HQ–OAR–2009–0491, U.S. Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include 2 copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.
- *Hand Delivery:* U.S. Environmental Protection Agency, EPA West (Air Docket), 1301 Constitution Avenue, NW., Room 3334, Washington, DC 20004, Attention Docket ID No. EPA–HQ–OAR–2009–0491. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2009–0491. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, avoid any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA East Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For questions regarding this Notice of Data Availability and the additional allocations information placed in the docket contact Brian Fisher, Clean Air Markets Division, USEPA Headquarters, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., *Mail Code:* 6204J, Washington, DC 20460; telephone number: (202) 343–9633; fax number: (202) 343–2359; e-mail *fisher.brian@epa.gov.*

SUPPLEMENTARY INFORMATION: Detailed background information describing the proposed rulemaking may be found in a previously published notice: Federal Implementation Plans to Reduce Interstate Transport of Fine Particulate Matter and Ozone (proposed Transport Rule); Proposed Rule, 75 FR 45210; August 2, 2010.

The information placed in the docket is also available for public review on the Web site for this rulemaking at *http://www.epa.gov/airtransport/.* If additional relevant supporting information becomes available in the future, EPA will place this information in the docket and make it available for public review on this Web site. This NODA does not extend the comment period for the proposed Transport Rule, which ended on October 1, 2010. This NODA also does not extend the comment period for the two NODAs supporting the proposed Transport Rule that were previously published in the **Federal Register**. The comment period for the NODA published September 1, 2010 closed on October 15, 2010. The comment period for the NODA published October 27, 2010 closed on November 26, 2010.

I. Additional Information on Submitting Comments

A. How can I help EPA ensure that my comments are reviewed quickly?

To expedite review of your comments by Agency staff, you are encouraged to send a separate copy of your comments, in addition to the copy you submit to the official docket, to Brian Fisher, Clean Air Markets Division, USEPA Headquarters, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., *Mail Code:* 6204J, Washington, DC 20460; telephone number: (202) 343–9633; fax number: (202) 343 2359; e-mail address *fisher.brian@epa.gov.*

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through EDOCKET, *regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI only to the following address: Gene Sun, Clean Air Markets Division, USEPA Headquarters, Ariel Rios Building, 1200 Pennsylvania Avenue, NW., *Mail Code:* 6204J, Washington, DC 20460; telephone number: (202) 343–9119; fax number: (202) 343–2359.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to: i. Identify the NODA by docket number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain your comments, why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns, and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Web Site for Rulemaking Information

The EPA has previously established a Web site for the proposed rulemaking at *http://www.epa.gov/airtransport.* The Web site includes the proposed rulemaking actions and other related information that the public may find useful in addition to a link to this NODA.

III. What is this Notice of Data Availability?

In the Transport Rule Notice of Proposed Rulemaking (NPR), EPA proposed that, until states submit and the Administrator approves State Implementation Plans (SIPs), Transport Rule Federal Implementation Plans (FIPs) would provide backstops to prohibit emissions in upwind states that significantly contribute to nonattainment or interfere with maintenance of certain National Ambient Air Quality Standards (NAAQS) in downwind states in compliance with section 110(a)(2)(D)(i)(I) of the Clean Air Act (CAA). This Notice of Data Availability (NODA) provides an opportunity for public comment on five issues related to the proposed Transport Rule and on data relevant to those issues. The relevant data has been placed in the rulemaking docket (Docket ID No. EPA–HQ–OAR–2009–0491) and on the Web at *http://www.epa.gov/airtransport.* Specifically, EPA is providing an opportunity for additional public comment on two methodologies for allocating allowances under the remedy proposed by EPA in the proposed Transport Rule and on supplemental data and information concerning the two allocation methodologies. EPA is also providing an opportunity for comment on: The implications of the alternative allocation methodologies for the proposed assurance provisions; an alternative approach to calculation of assurance provision allowance surrender requirements at the designated representative (DR) level; a methodology for allocating allowances to new units that choose to locate in Indian country in the Transport Rule region; and possible options for states wishing to submit State Implementation Plans (SIPs) providing for State allocation of allowances in the proposed Transport Rule trading programs.

The first issue on which EPA is soliciting comment relates to allowance allocations under the proposed limited interstate trading remedy. In the Transport Rule NPR, EPA proposed FIPs with a limited interstate trading remedy and requested comment on alternative remedies including intrastate trading and direct control. To implement the proposed limited interstate trading remedy, EPA would, among other things, require sources to hold emissions allowances equal to their emissions of certain air pollutants during each compliance period. Because EPA proposed FIPs in the Transport Rule, EPA also proposed a methodology for distributing (allocating) the allowances to individual existing units based on a combination of adjusted historic and projected emissions data and requested comment on possible alternative allocation methodologies.

This NODA describes two specific alternative allocation methodologies that would potentially be used to allocate allowances under FIPs in the final Transport Rule. These alternatives rely largely on historic heat input data to determine unit-level allocations. The NODA provides the underlying data, calculations, and resulting unit-level allocations obtained when each alternative is applied to the State budgets in the proposed Transport Rule. These alternative allocation methodologies could be used to implement the proposed interstate trading remedy or the intrastate trading remedy set forth in the proposed Transport Rule. In developing the final Transport Rule, EPA will consider these alternative allocation methodologies, as well as the allocation methodologies presented in the proposed Transport Rule. Further, issuance of this NODA does not preclude EPA from finalizing any of the remedies in the Transport Rule proposal, including limited interstate trading, intrastate trading, or direct control.

EPA received numerous public comments on the methodology in the proposed Transport Rule for allocating SO_2 Group 1, SO_2 Group 2, NO_X annual, and NO_X ozone season allowances to existing units. Many commenters suggested alternative allocation approaches. A number of commenters requested that EPA publish allocations and underlying data for any potential alternative allocation methodologies before issuing a final Transport Rule. The public comments received are available in the docket for the Transport

Rule (Docket ID No. EPA–HQ–OAR–2009–0491).

This NODA describes the two alternative allocation methodologies for existing units. Classification of units as existing units is discussed in section IV in this NODA. Units that are not classified as existing units would receive allocations of allowances based on the provisions for new unit allocations in the proposed Transport Rule. Note that the proposed Transport Rule does not discuss allocations to new units in Indian country; see section VII in this NODA for information on a potential allocation methodology for such units.

The alternative methodologies for existing unit allocations described in this NODA emerge from comments that EPA received during the comment period on the proposed Transport Rule. This NODA explains the two alternative allocation methodologies and identifies the unit-level data that serve as inputs for these alternative methodologies and the resulting existing-unit-level allocations obtained when the methodologies are applied to the State budgets provided in the proposal. Section V in this NODA lays out key issues that EPA encourages commenters to consider when submitting comments on the alternative allocation methodologies.

The unit-level allocations in this NODA are based on State emissions budgets in the proposed Transport Rule. It is important to note that final State budgets may differ from the proposed budgets because EPA is still in the process of updating its emissions inventories and modeling in response to public comments, including comments on the Integrated Planning Model (IPM). The final budgets will be based on the updated inventories and modeling. Thus, unit-level allocations in this NODA provide an indication of the proportional share of a State's budget that would be allocated to individual existing units if the alternative methodologies would be used. Any final allocations in the final Transport Rule would be based on the final State budgets and allocation methodology employed in the final rule. Because the unit-level allocations in the proposed Transport Rule and the unit-level allocations in this NODA are based on the same State budgets (*i.e.,* the budgets in the proposed Transport Rule), this approach allows commenters to compare how the allocation methodologies impact the distribution of allowances within a state.

This NODA only provides illustrative allocations to potential existing Transport Rule units. For purposes of this NODA, potential existing Transport Rule units are units that potentially meet the applicability criteria in the Transport Rule NPR (proposed §§ 97.404, 97.504, 97.604, and 97.704) and began commercial operation prior to January 1, 2009. Any unit that meets the proposed applicability criteria and began commercial operation on or after January 1, 2009 would be considered a new unit and receive allocations through the new unit set-aside described in the Transport Rule NPR because the unit would not have a full year of baseline data available at the time the Agency anticipates determining allocations to existing units. Such a new unit would not be reflected in the list of potential existing units for which illustrative allocations are presented in this NODA.

This NODA presents allocations based on the existing-unit portions of the state budgets under the proposed Transport Rule. In the proposal, the existing-unit portion of a state budget would be calculated as 97% of the total state budget in order to allot 3% to the new unit set-aside. EPA recognizes that the revised classification of units as existing units presented with these alternative allocation methodologies might affect the methodology used in the proposal that would establish the size of the new unit set-aside. EPA will consider comments submitted during this NODA's comment period when finalizing FIP allocations in the final Transport Rule and will address the issue of any effect of the finalized allocation methodology on the size of the new unit set-aside.

This NODA also requests public comment on four other issues. Specifically, the NODA requests comment on: an alternative approach to the calculation of assurance provision allowance surrender requirements (calculation at the DR level); the implications that the alternative allocation methods might have for the proposed assurance provisions; allocations to any new units that choose to locate in Indian country in a proposed Transport Rule state; and provisions for a state to participate in the Transport Rule trading programs through submission of a SIP (referred to as a full SIP) or to determine unit-level allocations under a FIP through submission of a SIP revision addressing only allocations (referred to as an abbreviated SIP).

EPA has placed in the docket for the proposed Transport Rule (Docket ID No. EPA–HQ–OAR–2009–0491) additional information relevant to the rulemaking, including illustrative unit-level allocations based on the state budgets provided in the Transport Rule proposal and supporting data discussed in this NODA. The information placed in the docket is also available for public review on the Web site for this rulemaking at *http://www.epa.gov/airtransport.*

It is also important to note that EPA is neither proposing any changes to nor accepting comment on the approach that will be used to identify each state's significant contribution and interference with maintenance and each state's emissions budget. EPA took comment on this approach and the resulting state budgets in the proposed Transport Rule. EPA also took comment on related modeling and emissions inventories in two subsequent NODAs (75 FR 53613; September 1, 2010, and 75 FR 66055; October 27, 2010).

For example, EPA is accepting comment on the alternative allowance allocation methodologies presented in this NODA, but not on whether EPA should use a remedy that requires the allocation of allowances. The allowances that are allocated to individual units are a tool that would be used to implement two of the remedies discussed in the proposed Transport Rule—the proposed limited interstate trading remedy and the alternative intrastate trading remedy; the allocation methodologies detailed in this NODA are simply variations on approaches for distributing those allowances to individual units.

Similarly, while EPA is accepting comment on discrete issues relating to implementation of the assurance provisions, EPA is not accepting comments on the need to have assurance provisions. The EPA took comment on this in the proposed Transport Rule and is now only requesting comment on discrete implementation issues concerning the assurance provisions. In particular, EPA is requesting comment on the implications that the alternative allocations methods might have for the assurance provisions and on the alternative of calculating assurance provision surrender on a DR-by-DR, rather than an owner-by-owner basis. This latter alternative of implementing the assurance provisions on a DR-by-DR basis is simply a variation in implementation of the proposed assurance provisions.

In summary, this NODA provides the public with the opportunity to comment on:

a. The two alternative allocation methodologies (described in section V in this NODA), including the major components of each alternative (*e.g.,* the

baseline period and formulas to be used in calculating allocations);

b. The underlying unit-level data and resulting allowance allocations for the alternative allocation methodologies based on the proposal's state budgets; and

c. The list of units used in applying the alternative allocation methodologies, including the classification of "existing" units.

This NODA also provides the public with the opportunity to comment on:

- The alternative of implementing the proposed assurance provisions on a DR-by-DR, rather than owner-by-owner basis (section VI in this NODA);
- The implications that the alternative allocation methodologies might have concerning the proposed assurance provisions of the Transport Rule and the reasonableness of using the proposed assurance provisions with these alternative allocation methodologies;
- Information regarding unit-level allowance allocations for any new units that choose to locate in Indian country in the proposed Transport Rule region in the future (section VII in this NODA); and
- Information regarding provisions for a state in the proposed Transport Rule region to participate in the Transport Rule trading programs through submission of a full SIP or to determine the unit-level allocations under a FIP through submission of an abbreviated SIP addressing only allocations (section VIII in this NODA).

During the comment period for this NODA, EPA will accept comments only on the issues explicitly addressed in this NODA. EPA is not requesting, and will not consider, comments on other aspects of the proposed Transport Rule (such as determinations concerning states' significant contribution and interference with maintenance and state budgets). EPA is not extending the comment period of the proposed Transport Rule, which closed on October 1, 2010. EPA also is not extending the comment period of the NODA published September 1, 2010, which closed on October 15, 2010, or the comment period of the NODA published on October 27, 2010, which closed on November 26, 2010.

IV. What are the sources of data in this NODA?

A. List of Potential Existing Transport Rule Units

Under the proposed Transport Rule, a covered Transport Rule unit is generally any stationary, fossil-fuel-fired boiler or stationary, fossil-fuel-fired combustion turbine located in a proposed Transport Rule state and serving at any time, since the later of November 15, 1990 or the start-up of the unit's combustion device, a generator with a nameplate capacity greater than 25 MWe producing electricity for sale. The proposed Transport Rule would exclude certain cogeneration units and solid waste incineration units from being covered Transport Rule units.

This NODA provides for comment on unit-level allocations (based on the budgets in the proposed Transport Rule) to potential existing covered units. For purposes of this NODA, a potential existing unit is assumed to be a unit that would potentially meet the proposed applicability criteria (i.e., the criteria in proposed §§ 97.404, 97.504, 97.604, and 97.704 in the proposed Transport Rule) for covered units and that commenced commercial operation prior to January 1, 2009. This cutoff date was chosen for existing units because it assured that at least 1 full year of historic data would be available to determine each existing unit's allocation. This NODA contains a list of, and sets forth allocations under the two alternative methodologies to, units that potentially meet the covered and existing unit criteria discussed above based on EPA's best available data.

To identify the potential existing Transport Rule units, EPA relied largely on data reported to EPA. To develop the list of potential existing Transport Rule units, EPA first included any fossil-fuel-fired unit serving a generator greater than 25 MWe producing electricity for sale that is in a proposed Transport Rule state and on line prior to January 1, 2009 and that reported emissions data in 2010 under at least one of the following ongoing EPA trading programs: Clean Air Interstate Rule (CAIR) NO_X or CAIR SO_2 annual trading program, Acid Rain Program (ARP), and CAIR NO_X ozone Season in Massachusetts, Connecticut, or Arkansas. Data reported to EPA under the CAIR and ARP programs meets the requirements of part 75 and has been certified as to its accuracy and completeness by the source's designated representative.

Next, EPA supplemented the list of units by using data from the Integrated Planning Model (IPM) v.4.10 to identify potential existing Transport Rule units that were not included in emissions data reported to EPA. Specifically, IPM's National Electric Energy Data System (NEEDS) was used to identify and obtain data for a subset of fossil-fuel-fired units serving generators greater than 25 MWe producing electricity for sale that are in a proposed Transport Rule state and were not reporting under one of the aforementioned ongoing EPA trading programs. NEEDS is a representation of all units capable of supplying electricity to the U.S. electric grid. This subset of units identified through NEEDS was then screened to remove units that were not potential existing Transport Rule units and thus not eligible to obtain allocations under one of the two alterative allocation methodologies discussed in this NODA.

In particular, if the unit was retired or in cold storage in 2010 or is a steam turbine at a combined cycle (CC) plant, then it was not included as a unit in the list of potential existing Transport Rule units.[1] The remaining units in this subset of units were added to the list. For instance, there were units in Nebraska, Kansas, and Oklahoma that were identified through NEEDS as being potential existing Transport Rule units that were not currently reporting under one or more of the aforementioned ongoing EPA trading programs because the units were not ARP units and were not in a CAIR state. Finally, a small number of units were added to or removed from the list based on comment and supporting data previously submitted to the EPA during the comment period on the proposed Transport Rule by the unit owner or operator.

As described above, the list of potential existing Transport Rule units is based on EPA and NEEDS data. Units identified using the EPA and NEEDS databases were included in the list of potential existing Transport Rule units if they were in one of the following states covered by the proposed Transport Rule: Arkansas, Alabama, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Iowa, Indiana, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New York, North Carolina, Oklahoma, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, West Virginia, and Wisconsin.

EPA notes that inclusion of a unit in, or exclusion of a unit from, the list of potential existing Transport Rule units presented in this NODA reflects only a preliminary assessment of the applicability of the proposed Transport Rule and in no way suggests that EPA has made a determination about the

[1] In NEEDS, the combustion turbine and steam turbine associated with a single CC plant are generally represented as two separate generating units. The steam turbine at a CC does not combust fuel, though, and should not be included in the list of potential existing Transport Rule units.

applicability of the proposed Transport Rule to any unit. As discussed above, the list of units developed for this NODA enables EPA to calculate illustrative allowance allocations for potential existing units based on the alternative methodologies presented. Moreover, this list may be used by EPA to calculate unit-level allocations in the final Transport Rule. While allocations calculated for the final Transport Rule would be based on the best available data provided to EPA by the time of the calculation, the applicability of the final Transport Rule to an individual unit would be determined based on all relevant data, whether or not EPA would have such data at the time that allocations would be calculated. In fact, because any list of units developed for purposes of allowance allocation may not be entirely consistent with applicability determinations made in the future, the proposed Transport Rule (proposed §§ 97.411(c), 97.511(c), 97.611(c), and 97.711(c)) would establish procedures to be applied when the Administrator would determine that a unit allocated allowances would turn out not to actually be a proposed Transport Rule unit. For example, under these proposed procedures, if such a determination would be made after EPA's recordation of the allowance allocation but before EPA's deduction of allowances for compliance with the requirement to hold allowances covering emissions, the Administrator would deduct the recorded allowances and transfer them to a new unit set-aside for the appropriate state.

If owners and operators believe that their units that are included in the list of potential existing units should not be included, these owners and operators should submit comments on this NODA informing EPA why the units should not be in the list. If owners and operators believe that their units should be, but are not, treated as potential existing Transport Rule units and included in the list of such units provided by this NODA, these owners and operators should submit comments on this NODA, informing EPA that the units should be added to the list and allocated allowances and providing support for this addition to the list. The data necessary for calculating allowance allocations under the two alternative allocation methodologies should also be provided. A unit that would not be allocated allowances as an existing unit because of the unit's exclusion from the list of potential existing Transport Rule units could ultimately be determined to be a Transport Rule unit. Under the proposed Transport rule, each Transport Rule unit would be subject to the allowance-holding requirements of the Transport Rule regardless of whether the unit would be allocated any allowances as an existing unit.

B. Historic Heat Input and Emissions Data Used in the Allowance Allocation

The alternative allocation methodologies presented in this NODA draw on historic heat input and historic emissions for potential existing Transport Rule units. For units subject to one of the aforementioned ongoing EPA trading programs and included in the list of potential existing Transport Rule units, EPA used reported heat-input data from the EPA database for the years 2005 through 2009. For these same units, EPA used reported emissions from the EPA database for the years 2003 to 2009. These data are publicly available through EPA's data and maps at *http://camddataandmaps.epa.gov/gdm/.*

For units included in the list of potential existing Transport Rule units that were not reporting under one of the aforementioned ongoing EPA trading programs, EPA used historic heat input and emissions data from Energy Information Administration (EIA) forms 767, 860, 906, 920, and 923. These data are publicly available at *http://www.eia.doe.gov/cneaf/electricity/page/data.html.*

V. What are the alternative allocation methodologies and on what is EPA requesting comment?

(a) Why is EPA considering heat input-based allocation methodologies?

In the proposed Transport Rule, EPA proposed a methodology for allocating allowances to potential existing Transport Rule units. That methodology is based on a combination of adjusted historic and adjusted projected emissions data. EPA received a large number of public comments from a variety of commenters suggesting alternative allocation methodologies. One of the most frequently suggested metrics for allocation was historic heat input. Commenters stated that using historic heat input as the basis for allocations has the following advantages:

(i) Historic heat input data are more likely to be accurate at a unit level than projected unit-level emissions and are generally based on quality-assured data reported by sources from continuous monitoring systems.

(ii) Historic heat input data are fuel-neutral.

(iii) Historic heat input data are emissions-control-neutral and thus do not yield reduced allocations for units that installed or are projected to install pollution control technology.

EPA is considering the above-listed points made by commenters regarding heat-input based allocations.

Numerous commenters also noted that EPA has broad authority to implement alternative allocation methodologies under sections 110(a)(2)(D)(i)(I) and 302(y) of the Clean Air Act (CAA).[2] EPA agrees with commenters that the Agency has significant discretion in this area. Neither the CAA nor the D.C. Circuit Court's opinion in *North Carolina* v. *EPA (531 F.3d 896 (D.C. Cir. 2008),* specifies a particular methodology that EPA must use to allocate allowances to individual units. The statute focuses on prohibiting emissions within the state that significantly contribute to or interfere with maintenance. Under CAA section 110(a)(2)(D)(i)(I), states have significant discretion to develop a control program in a SIP that achieves this objective and EPA has similarly wide latitude when issuing a FIP. Moreover, the definition of FIP in section 302(y) of the Act clarifies that a FIP may include "enforceable emission limitations or other control measures, means or techniques (including economic incentives, such as marketable permits or auctions of emissions allowances)" but does not require EPA to use any particular methodology to allocate allowances under a FIP trading program. In light of this lack of direction concerning allowance allocation, EPA has significant discretion to select an allocation methodology that is reasonable and consistent with the goals of CAA section 110(a)(2)(D)(i)(I) of the Act, including improving long-term air quality and encouraging cost-effective emissions reductions.

EPA believes the allocation methodologies presented in the proposed Transport Rule as well as those presented in this NODA all meet that test. Section 110(a)(2)(D)(i)(I) of the CAA requires that emissions "within a state" that significantly contribute to nonattainment or interfere with maintenance in another state be

[2] CAA section 302(y) defines the term "Federal implementation plan" as follows:

Federal implementation plan.—The term "Federal implementation plan" means a plan (or portion thereof) promulgated by the Administrator to fill all or a portion of a gap or otherwise correct all or a portion of an inadequacy in a State implementation plan, and which includes enforceable emission limitations or other control measures, means or techniques (including economic incentives, such as marketable permits or auctions of emissions allowances), and provides for attainment of the relevant national ambient air quality standard.

prohibited. In the proposed Transport Rule, EPA analyzed each individual state's significant contribution and interference with maintenance and calculated budgets that represent each state's emissions after the elimination of those prohibited emissions. The methodology used to allocate allowances to individual units in a particular state has no impact on that state's budget or on the requirement that the state's emissions not exceed that budget plus variability. Regardless of the allocation methodology used, all emissions in each covered state that significantly contribute to nonattainment or interfere with maintenance in another state will be prohibited. In sum, the allocation methodology has no impact on the rule's ability to satisfy the statutory mandate of CAA section 110(a)(2)(D)(i)(I) to eliminate significant contribution and interference with maintenance in downwind states.

EPA believes that a historic-heat-input-based allocation methodology is consistent with the goals of CAA section 110(a)(2)(D)(i)(I). The proposed Transport Rule would set state budgets reflecting the overall emission reductions necessary for each respective state to eliminate significant contribution and interference with maintenance in downwind states. The initial allocation of allowances under each state budget to existing units on the basis of the units' historic heat input would yield a distribution of allowances putting relatively greater burden on the higher-emission-rate units to reduce emissions or purchase additional allowances in order for the units to be in compliance with the proposed Transport Rule trading programs. This pattern would result because heat-input-based allocations would provide the same share of allowances to units with the same heat input even though the higher-emission-rate units would require more allowances in order to cover their emissions than would lower-emission-rate units. EPA believes that, because higher-emission-rate units generally are responsible for a greater share of a state's total emissions and thus bear greater responsibility for a states' significant contribution and interference with maintenance, this distribution of burden is consistent with the goals of CAA section 110(a)(2)(D)(i)(I).

The proposed Transport Rule includes four trading programs (SO_2 Group 1, SO_2 Group 2, NO_X annual, and NO_X ozone season). EPA requests comment on whether the allocation methodology chosen for each of the four trading programs must be the same or whether it would be reasonable to allocate using different methodologies for the different programs. EPA also requests comment on rationales for using different methodologies for the different trading programs.

(b) What are the alternative heat input allocation methodologies and how would they be applied?

This NODA provides an opportunity for public comment on the two alternative allocation methodologies described below. To make it easier for commenters to compare the methodologies presented in this NODA with the methodology proposed in the proposed Transport Rule, EPA is providing in the rulemaking docket for the Transport Rule (and on the EPA *Web site*) data showing the unit-level allocations that would result if the methodologies were applied to allocate allowances from the state budgets in the proposed Transport Rule. As noted above, these budgets may be revised in the final Transport Rule and thus the unit-level allocations (based on 97% of the respective state budgets) in this NODA would not necessarily be the unit-level allocations in the final rule.

The alternative allocation methodologies described in this NODA represent two variations of historic-heat-input-based allocations. For each alternative allocation methodology, the underlying data and resulting allocations are set forth in allocation tables located at *http://www.epa.gov/airquality/transport/actions.html* and in the public docket for the Transport Rule. The calculations used to derive the unit-by-unit allocations for each alternative option are described below.

Option 1 described below would allocate a state's existing unit budget (*i.e.,* 97% of its budget) based on each unit's proportionate share of the state's total historic heat input.

Option 2 would yield the same initial allocation pattern as Option 1 (based on historic heat input) but would then add a constraint (*i.e.,* a limit on allocations) premised on a unit's reasonably foreseeable maximum emissions under the proposed Transport Rule trading programs.

Option 1—Historic Heat Input Approach

This option would establish a baseline historic heat input value for each potential existing Transport Rule unit and allocate to that unit a share of available allowances under each proposed Transport Rule program equal to the unit's percentage share of the total baseline historic heat input for all potential existing Transport Rule units in the state. As with all allocation approaches under consideration by EPA, this option would be applied to each state separately using the portion of that state's budget available for potential existing Transport Rule units in that state. Allocations under this approach for each existing unit would be determined by applying the following steps.

1. For each unit in the list of potential existing Transport Rule units, annual heat input values for the baseline period of 2005 through 2009 would be identified using data reported to EPA or, where EPA data is unavailable, EIA. As discussed above, for purposes of this NODA, potential existing Transport Rule units are units that potentially meet the applicability criteria in the proposed Transport Rule and began commercial operation prior to January 1, 2009. A number of units would not have non-zero data for one or more of the baseline years (e.g., a unit that came on line after 2005 but before 2009) and would be assigned a zero value for each of those years in the baseline. (Step 2 explains how such zero values would be treated in the calculations.) This option would use a five-year baseline in order to improve representation of a unit's normal operating conditions over time. EPA requests comment on the existing-unit cut-off date of January 1, 2009 for purposes of this NODA.

2. For each unit, the three highest, non-zero annual heat input values within the 5 year baseline would be selected and averaged. Selecting the three highest, non-zero annual heat input values within the five-year baseline would reduce the likelihood that any particular single year's operations (which might be negatively affected by outages or other unusual events) would determine a unit's allocation. If a unit would not have three non-zero heat input values during the 5 year baseline period, EPA would average only those years for which a unit does have non-zero heat input values. For example, if a unit has only reported data for 2008 and 2009 among the baseline years and the reported heat input values are 2 and 4 mmbtus respectively, then the unit's average heat input used to determine its pro-rata share of the state budget would be (2+4)/2 = 3.

3. Each unit would be assigned a baseline heat input value calculated as described in step 2 above. This baseline heat input value is referred to in the data tables in the rulemaking docket and on the *Web site* referenced previously, and in the remainder of this NODA, as the "three-year average heat input".

4. The three-year average heat inputs of all potential existing Transport Rule units in a state would be summed to obtain that state's total "three-year average heat input".

5. Each unit's three-year average heat input would be divided by the state's total three-year average heat input to determine that unit's share of the state's total three-year average heat input.

6. Each unit's share of the state's total three-year average heat input would be multiplied by the state's existing-unit portion of the state budget (i.e., 97% of the state budget) to determine that unit's allocation.

Option 2—Emissions-Rate-Informed Historic Heat Input Approach

This option retains the historic-heat-input-based approach but adds a constraint premised on a unit's reasonably foreseeable maximum emissions under the proposed Transport Rule trading programs. For the majority of units, the historic heat input-based allocation will not be sufficient to cover historic emission levels; this reflects the shared burden on units to reduce emissions in order to eliminate the state's significant contribution and interference with maintenance. Heat input-based allocations only exceed historic emissions for units at the lower end of the range of historic emission rates for the pollutant involved. For these lower-emission rate units, this option would establish, based on historic data, a reasonably foreseeable maximum emissions level reflecting a reasonable upper-bound capacity utilization factor and a well-controlled emission rate that all units (regardless of the type of fuel they combust) can meet for the pollutant. For those units whose heat-input-based allocations would exceed historic emissions, this option would limit the historic-heat-input-based allocations to this maximum emissions level so that the units would not be allocated allowances in excess of their reasonably foreseeable maximum emissions. EPA believes that this approach would result in a reasonable initial distribution of allowances that is consistent with the goals of CAA section 110(a)(2)(D)(i)(I).

1. The same 6 steps outlined above in Option 1 would be applied to each unit.

2. A seven-year (2003 through 2009) historic emissions baseline would be established for SO_2, NO_X, and ozone season NO_X based on data reported to EPA or, where EPA data is unavailable, EIA data. This approach would use this seven-year historic emissions baseline in order to reflect unit-level emissions before and after the promulgation of the CAIR.

3. For each unit, the maximum annual historic SO_2 and NO_X emissions would be identified within the seven-year baseline. Similarly, the maximum ozone season NO_X emissions from the seven-year baseline for each unit would be identified. These values are referred to as the "maximum historic baseline emissions" for each unit.

4. For each unit whose historic-heat-input-based allocation exceeds its maximum historic baseline emissions, EPA would determine an emission level (referred to as the "well-controlled-rate maximum" for each unit) calculated as:

a. For a unit reporting maximum hourly heat input to EPA, the reported figure multiplied by a well-controlled emission rate of 0.06 lbs/mmBtu for SO_2 and 0.06 lbs/mmBtu for NO_X. For a unit that does not report maximum hourly heat input to EPA, EPA would estimate the unit's maximum hourly heat input by multiplying the unit's heat rate and capacity values (from NEEDS in IPM version 4.10). These well-controlled emission rates of 0.06 lbs/mmBtu for SO_2 and NO_X represent the lowest annual emission rates assumed achievable when state-of-the-art pollution control technologies are installed at coal units in the IPM modeling.[3]

b. The unit's maximum hourly heat input determined in step 4.a above would be multiplied by 8,760 hours (annual) or 3,672 hours (ozone season) to get an annual or ozone season emissions level at 100% utilization.

c. The unit's emissions level at 100% utilization determined in step 4.b above would be multiplied by the reasonable upper-bound capacity factor for each technology type. These upper-bounds would be calculated as the utilization values at the 95th percentile in each technology class.[4] These 95th percentile values are set forth in the table below.

TABLE I—SUMMARY OF CAPACITY FACTORS AT 95TH PERCENTILE

["Reasonable Upper-Bound Capacity Factor"]

Technology class	Annual	Ozone season
Coal-fired boiler	0.87	0.89
Combined cycle	0.70	0.73
Combustion turbine	0.14	0.22
Oil or gas fired boiler	0.46	0.55
Other	0.71	0.75

5. If a unit identified in step 4 has an historic-heat-input-based allocation greater than both its maximum historic baseline emissions (as determined in step 3) and its well-controlled-rate maximum (as determined in step 4), then its allocation (referred to as the unit's "reasonable foreseeable maximum emissions level") would equal the higher of these two values.

6. The difference (if positive) under step 5 between a unit's historic-heat-input-based allocation and its "reasonable foreseeable maximum emissions level" would be reapportioned on the same basis as described in step 1 to units whose historic-heat-input-based allocations are not revised under step 5. Steps 4, 5, and 6 would be repeated with each revised allocation distribution until the entire existing-unit portion of the state budget (*i.e.,* 97% of the state budget) would be allocated.

The table below provides an example of application of the steps in Option 2.

[3] As identified in EPA's documentation of EPA Base Case v.4.10 model available at *http://www.epa.gov/airmarkets/progsregs/epa-ipm/docs/v410/Chapter5.pdf.* These emission rates are based on the floor rates used in IPM modeling and are intended to reflect the lower bound of emission rates that suppliers are willing to guarantee when installing state-of-the-art pollution control equipment (selective catalytic reduction (SCR) and flue-gas desulfurization (FGD)).

[4] Capacity factors were determined as follows. (1) Using data reported to EPA by source owners and operators under the aforementioned ongoing EPA trading programs, EPA determined, for units reporting electrical output, the capacity factor for each unit for each year of operation during 2000–2009 by dividing gross electrical output by maximum hourly load times 8,760 hours/year and, for units reporting steam output (KLBsteam), dividing total mass of steam produced by the maximum rate times 8,760 hours; (2) EPA then identified each unit's plant type based on how the unit was listed in NEEDS in IPM version 4.10 (e.g., coal steam, combined cycle, combustion turbine, oil/gas steam, and "other"). "Other" comprised fossil waste, biomass, tires, and landfill gas. (3) Using the units' calculated annual capacity factors, EPA identified the 95th percentile value of capacity factor for each plant type. Resulting values are in Table 1 above. This analysis is based largely on the same data and methodology used in the Capacity Factor Analysis Technical Support Document located at *http://www.epa.gov/airquality/transport/pdfs/TSD_capacity_factors_analysis_for_new_units_7–6–10.pdf.* However, in this analysis EPA expanded the data set to include all units, whereas the previous analysis had examined solely CAIR units online after 1999 because its focus had been on new units.

TABLE II—DEMONSTRATION OF ALLOCATIONS USING OPTION 2 IN A TWO-UNIT STATE WITH A 30-TON STATE BUDGET

	Step 1	Step 2 & 3	Step 4	Step 5 (greater of step 3 result or step 4 result)	Step 6
	Heat-input-based allocation	Historic maximum baseline emissions	Well-controlled-rate maximum	Reasonable foreseeable maximum emissions level	Final allocation
Unit A	10	4	6	6	6
Unit B	20	40	N/A	N/A	24

(c) What allocations-related data and information are the EPA making available for review and comment?

EPA has used the best available data to develop a list of potential existing Transport Rule units and to calculate illustrative allowance allocations for each such unit under the two alternative allocation methodologies discussed in this NODA. However, through the NODA, EPA is giving unit owners and operators and the public in general the opportunity to offer comments on individual units' inclusion in or exclusion from such list and—for units that EPA included on the list or that commenters believe should be included on the list—on the data needed for allocation calculations (including any necessary data that EPA has not provided in this NODA) under the two alternative allocation methodologies and the allocations that result or should result from such calculations.

For units on the list of potential existing Transport Rule units, EPA is providing for the years 2003 through 2009 the relevant EPA-reported heat input and emissions data under the aforementioned ongoing EPA trading programs and, for those units not reporting under these programs, heat input and fuel data in EIA databases. EPA is also providing the Agency's calculations using these data in the two alternative allocation methodologies described in this NODA.

In addition to comments on the list of potential existing Transport Rule units, allocation-related data, and calculations of allocations, EPA requests comments on the appropriateness of the alternative allocation methodologies and their implications for rule implementation. In particular, EPA encourages commenters to address the following:

- Are the alternative allocation methodologies clear and easy to understand?
- Do these alternative methodologies raise any implementation concerns, such as concerns about feasibility of implementing the methodology?
- How are these methodologies consistent with the goals of CAA section 110(a)(2)(D)(i)(I)?
- Do these alternative methodologies yield a reasonable distribution of allowances?
- Should the same methodology be used for each of the proposed Transport Rule trading programs, or should a different methodology be used for one or more such trading programs?

(d) Why is the EPA providing opportunity to comment on these allocation-related data and information?

Through this NODA, EPA is providing owners and operators, states and the public in general the opportunity to comment on the allocations-related data and information described above in order to ensure that we use the best available data in the Transport Rule FIP allocation process. For example, the heat input and emissions data used to calculate allocations came from data reported to EPA and EIA, and a unit owner or operator (or other member of the public) should comment if he or she sees any discrepancy between the data reported for the unit and the heat input and emissions data used in calculating the allocations in this NODA. Such comment should include the data that the commenter believes EPA should use and the source of that data and where else the data may be reported to the Federal government. EPA is also providing an opportunity to comment on the calculations using the alternative allocation methodologies and the data in order to ensure the accuracy of the calculations.

The allocations presented in this NODA are also based on the list of potential existing Transport Rule units developed using data currently available to EPA. As discussed above, a unit's inclusion on or exclusion from this list does not constitute a determination of the applicability of the proposed Transport Rule to the unit, but rather reflects EPA's preliminary application of the applicability provisions in the proposed Transport Rule. In order to ensure the accuracy of the allocation calculations, the EPA is providing this opportunity for source owners and operators, and the public in general, to (1) comment on units' inclusion in, or exclusion from, the allocation tables in the NODA and the data on which the inclusion or exclusion is or should be based, (2) comment on the heat input and other data used or that should be used to calculate the allocations and the resulting allocations, and (3) submit corrections of the data or supplementary data. While EPA requests that owners and operators, states, and other members of the public who believe that a unit has been incorrectly included in or excluded from the allocation tables submit a comment (including any supporting data). EPA is not requesting, and will not consider, any comments on the proposed applicability provisions themselves (proposed §§ 97.404, 97.504, 97.604, and 97.704).

The addition or removal of existing units to or from a state's list of potential existing Transport Rule units will not impact the size of the state budget. EPA's responses to comments on this NODA concerning the list of potential existing Transport Rule units and the data to be used to allocate to specific units and EPA's updated modeling and responses to comments on the proposed Transport Rule concerning the proposed state budgets may result in the individual units receiving different shares of the applicable state budget than reflected in the allocation tables.

(e) What supporting documentation do I need to provide with my comments?

While we will consider all comments on issues that are within the scope of this NODA, these comments should be supported with appropriate documentation. Supporting documentation can include, but is not limited to, spreadsheets, explanations of why you believe the data on such spreadsheets are accurate (*e.g.,* the

quality assurance of the data), and information on the data source.

In general, we do not anticipate revisions to unit heat input and emissions data reported to EPA under the ARP and CAIR programs since, in submitting the data under these programs, a source's DR has already certified the accuracy and completeness of the data. However, we will consider any comments. For example, a source's DR may provide evidence that we improperly calculated heat input at the unit-level if the heat input was actually measured at another location (such as a common stack). As a further example, a source's DR may demonstrate that the data provided in this NODA are not consistent with the data reported to EPA for compliance with the ARP or CAIR programs. In that case, the commenter should explain why the data values in EPA's data files are incorrect and should document and explain the new data values.

Similarly, in general, we do not anticipate revisions to data reported to EIA since such data were submitted to meet regulatory reporting requirements. However, we will consider any comments on the data as reported, as well as on any calculation in which we used the data for purposes of this NODA.

VI. On what aspects of the proposed assurance provisions is EPA requesting comment?

(a) Whether the Assurance Provision Allowance Surrender Requirement Should be Calculated on a Designated Representative Basis

Under the proposed Transport Rule, the assurance provisions would be triggered for a state for a given year if total emissions for covered units in the state for the year exceed the state assurance level (*i.e.,* the state budget plus the state's variability limit). As proposed, if this level were exceeded, the assurance provision allowance surrender requirement would be imposed on certain owners of covered units in the state and calculated on an owner-by-owner basis. Specifically, each owner whose share of the state's total covered-unit emissions exceeded the owner's share of the state assurance level would have to surrender a proportionate share of the state's exceedance. In this NODA, EPA is requesting comment on whether the surrender requirement should be imposed on certain owners and operators of covered units in the state but calculated on a DR-by-DR basis, rather than on an owner-by-owner basis.

Under this alternative approach, the calculation of shares of covered-unit emissions and of the state budget plus variability would be performed for each group of covered units having a common DR. EPA would use the DR as of the allowance transfer deadline for a given control period (generally March 1 following the control period for the proposed Transport Rule NO_X and SO_2 annual trading programs and December 1 following the control period for the proposed Transport Rule NO_X ozone season trading program) for determining assurance provision surrender requirements. In order to be treated as a group of covered units for this purpose, the units would have to be located at sources in the state with the same individual as their DR (not alternate designated representative).[5]

For each such group of covered units in the state, the DR's share of the state's covered-unit emissions (*i.e.,* the total emissions of the covered units at the group of covered sources having that DR) for the year and the DR's share of the state assurance level (*i.e.,* the total allocations for the covered units at such sources plus the units' proportionate share of the state variability limit) would be calculated. The owners and operators represented by a common DR whose share of state covered-unit emissions exceeded his or her share of the state assurance level would all be subject to the DR's proportionate share of the proposed assurance provision allowance surrender requirement (*i.e.,* the requirement that one allowance be surrendered for each ton by which the state's total covered-unit emissions would exceed the state assurance level). The DR's share of the surrender requirement would equal the amount by which the DR's share of the state's total covered-unit emissions exceeded the DR's share of the state assurance level, divided by the sum of all such exceedances for all DRs for covered units in the state. The owners and operators would be collectively and individually liable for making this allowance surrender and would determine themselves how to divide up the actual surrender. This would be similar to the way that all owners and operators of a covered source that fails to hold allowances covering the source's emissions are collectively and individually liable for an excess emissions penalty. The owners and operators subject to the allowance surrender requirement would be required to transfer the necessary amount of allowances by the specified deadline to an assurance account created by EPA for these owners and operators.

EPA believes that imposing the proposed assurance provision allowance surrender requirement at the DR level, rather than owner level, is more straightforward and consistent with information already provided to EPA and potentially provides owners and operators with more flexibility than under the approach in the proposed Transport Rule. Other requirements under the proposed Transport Rule trading programs (*e.g.,* the requirement to monitor and report emissions and to hold allowances covering emissions) would be imposed on a unit-by-unit or source-by-source basis. Consequently, EPA would not generally obtain detailed ownership information (such as percentage ownership in individual units) and would have to collect such information only in order to implement the owner-by-owner approach in the assurance provisions in the proposed Transport Rule. The DR approach for calculating the assurance provision surrender requirements would eliminate the need to collect detailed ownership information and would also avoid the complications arising from having to divide up units' emissions and allocations among partial owners of the units. In addition, the DR approach would apply to units with a common DR even in the case where the units involved did not have a common owner or operator. This would allow owners and operators to designate a common DR for all of the sources at which their units are located and thereby obtain the increased flexibility of having the assurance provisions apply to the entire group. Like the proposed approach of calculating the assurance provision surrender requirements on an owner-by-owner basis, the alternative approach of calculating such requirements on a DR-by-DR basis could be applied under any of the allocation methods under consideration. In developing the final Transport Rule, EPA will consider both approaches.

[5] Under proposed §§ 97.413, 97.513, 97.613, and 97.713, the owners and operators of a source could designate one individual as the DR, who would represent and legally bind them in all matters concerning the proposed Transport Rule trading programs. Under these provisions, these owners and operators also could designate another individual as the alternate designated representative, who could act on behalf of the DR and would legally bind the DR and thus the owners and operators. EPA notes that the concept of requiring representation of source owners and operators by a DR has been used in prior EPA trading programs, including the ARP and CAIR trading programs.

(b) Whether the Overall Assurance Provision Approach Should Be Maintained if One of the Alternative Allocation Methodologies Is Used in the Final Transport Rule

EPA received several comments on the proposed Transport Rule concerning whether the proposed assurance provisions should be changed if the proposed allocation methodology were changed. For the reason discussed below, EPA does not believe that a change in allocation methodology would necessitate any changes in the assurance provisions set forth in the proposed Transport Rule. In the unlikely event that a state exceeds its state assurance level, only the owners and operators whose shares (or the owners and operators whose common DR's share) of the state's emissions exceed the owners' and operators' (or the common DR's) share of the state assurance level would be subject to the allowance surrender requirement.

While EPA believes the likelihood of triggering assurance provisions would be low for the reasons provided in the proposed Transport Rule (75 FR 45314), the assurance provisions must have an enforcement mechanism to be effective. The assurance provision allowance surrender requirements exist to ensure that the state budgets plus variability limits (the state assurance levels) would not be exceeded in any state. These surrender requirements identify what penalties would apply if the assurance level were to be exceeded.

EPA believes that a change to the allocation methodology would not necessitate any changes to the assurance provisions in the proposed Transport Rule for the following reason. The proposed Transport Rule explained that, in the event that a state's total emissions would exceed the state budget plus variability, those groups of units (whether grouped by owner as in the proposal or by common DR as discussed in this NODA) with an analogous exceedance (*i.e.,* those groups of units with total emissions exceeding their total allowance allocations plus their shares of state variability) would reasonably be viewed as accounting for the state's exceedance and thus should be subject to proportionate shares of the allowance surrender penalty calculated as one allowance to be surrendered for each ton of the state's exceedance. Even under a different allowance allocation methodology than the allocation methodology proposed in the Transport Rule, it would continue to be the case that groups of units with greater emissions than their allocations plus share of state variability would reasonably be held responsible for the state's excess of emissions over the state assurance level. EPA believes that any state that would exceed its state assurance level would likely do so because not all units would have made the reductions necessary to eliminate the state's contribution to nonattainment or interference with maintenance. Moreover, the groups of units with emissions exceeding their allocations plus share of variability would be the units that were most likely to have contributed to the state's exceedance of its state assurance level and thus to the state's triggering of the assurance provisions. Consequently, it would be reasonable to penalize those groups of units (whether grouped by owner or by common DR)—through application of the assurance provision allowance surrender requirement—for the state's exceedance.

EPA received comments that proposed assurance provision penalties should be delinked from allocations and that a different method of imposing such penalties should be applied. However, as discussed above, the Agency still believes that the proposed assurance provisions provide a reasonable way of identifying those sources within a state that most likely contributed to, and share responsibility for, any triggering of the assurance provisions. EPA also believes that the proposed assurance provisions, with calculation of the allowance surrender requirements made on an owner-by-owner basis (as proposed) or on a DR-by-DR basis (under the alternative discussed in this NODA) provide a reasonable way of distributing proportionate shares of the responsibility for eliminating a state's significant contribution and interference with maintenance. However, EPA is requesting comment in this NODA on the implications of retaining the proposed assurance provisions (with the surrender requirements calculated on an owner-by-owner or DR-by-DR basis) in conjunction with the alternative allocation methodologies presented. While EPA believes that the overall approach for the assurance provisions would still be appropriate with an alternative allocation methodology, the Agency may reevaluate some of the details of those provisions, for example, the proposed variability limits for each state, the treatment of new units that have not yet been allocated allowances, and the allowance surrender levels when it promulgates the final Transport Rule.

VII. Allocations to New Covered Units in Indian Country in the Future

EPA received comments that it did not adequately consider opportunities for Indian tribes to enter into any of the trading programs in the Transport Rule proposal. This section explains and provides an opportunity to comment on some options for allocating allowances to covered units that might in the future be constructed in Indian country. In addition, EPA has initiated a process to consult with any interested tribes on issues related to the proposed Transport Rule and will conclude this consultation before making any final decisions on this issue. EPA will take into consideration additional input it receives as part of the tribal consultation process.

In the Tribal Authority Rule, EPA determined that it was appropriate to treat eligible Indian tribes in the same manner as states for purposes of the prohibitions and authority contained in CAA section 110(a)(2)(D). *See* 63 FR 7254, 7260; February 12, 1998. Tribes are not, however, required to submit implementation plans. As explained in EPA's regulations outlining Tribal Clean Air Act authority, EPA is authorized to promulgate FIPs for Indian country as necessary or appropriate to protect air quality if a tribe does not submit and get EPA approval of an implementation plan. *See* 40 CFR 49.11(a). Presently, there are no covered sources located in Indian country in the region covered by the proposed Transport Rule. In the event of the planned construction of such a source in Indian country in the proposed Transport Rule region, EPA intends to work with the relevant Tribal government to ensure that Tribal concerns regarding allocations are addressed and, at the same time, that emissions from the source do not violate CAA section 110(a)(2)(D)(i)(I). In the case of a covered source locating in the future in Indian country in the proposed Transport Rule region, the EPA anticipates that the Transport Rule FIPs would require the covered source to meet the requirements of the proposed EPA administered Transport Rule trading programs if those programs are finalized.

EPA also anticipates that any covered units at a covered source locating in Indian country in the proposed Transport Rule region would be eligible to receive allowances from the EPA-administered new unit set-aside under the FIPs for the proposed Transport Rule state in which the area of Indian country is located. Identical to the approach proposed in the Transport Rule for other new covered units, the

owner or operator of units in Indian country in the proposed Transport Rule region could request allocations from the EPA-administered new unit set-aside by a specified deadline each year. The allocations distributed by EPA under the FIPs would equal that unit's emissions for the control period in the preceding year (75 FR 45322). EPA has not currently identified a basis for treating new units locating in Indian country without initial SO_2 or NO_X allowance allocations differently from new units locating elsewhere in the Transport Rule region without initial allowance allocations.

As part of this NODA, EPA is requesting comment on all aspects of how allowances for covered units locating on tribal lands should be allocated. Specifically, EPA requests comment on how, in the final Transport Rule FIPs, EPA should allocate allowances to any covered units that are constructed in Indian country in the proposed Transport Rule region in the future. EPA is also requesting comment on how any such allowance allocation methodology should, if at all, affect state budgets or allowance allocations to existing units and what further action, if any, EPA should take to work with Tribes and affected states to resolve this issue in the event any covered units are constructed in Indian Country in the proposed Transport Rule region. Finally, EPA requests comment on how such allocations should be addressed in a state that has submitted a SIP providing for state allocation of allowances in the proposed Transport Rule trading programs.

VIII. Provisions for States To Submit Transport Rule SIPs or Abbreviated SIPs Providing for State Allocation of Allowances in Proposed Transport Rule Trading Programs

The proposed Transport Rule explains that "by promulgating these Transport Rule FIPs, EPA would in no way affect the right of states to submit, for review and approval, a SIP that replaces the Federal requirements of the FIP with state requirements. In order to replace the FIP in a state, the state's SIP must provide adequate provisions to prohibit NO_X and SO_2 emissions that contribute significantly to nonattainment or interfere with maintenance [of the 1997 ozone and 1997 and 2006 $PM_{2.5}$ NAAQS] in another state or states * * * EPA is taking comment on all aspects of how a state could replace the Transport Rule FIP with a SIP and on what the SIP approval criteria should be." 75 FR 45342.

EPA received comments suggesting that EPA allow states to replace EPA's allowance allocation provisions in the proposed Transport Rule trading programs by state-developed allocation provisions. Commenters referenced the two alternatives provided to states by EPA in the CAIR trading programs where: (1) EPA adopted a rule and model trading regulations under which states that adopted, as state SIP trading programs, the model regulations (with only certain limited changes allowed, *e.g.,* in the allocation provisions) could participate in the EPA-administered CAIR trading programs; and (2) EPA adopted a rule allowing states to adopt in SIPs provisions replacing only certain provisions in the CAIR FIPs (*e.g.,* the allocation provisions) and to remain in the CAIR trading programs under the CAIR FIPs. Under both approaches, the covered units in the state participated in the CAIR trading programs, albeit with state-, rather than EPA-, determined allocations.

In the comment period on the proposed Transport Rule FIP, EPA received comments supporting these two types of approaches for allowing states to replace EPA allocations under the proposed Transport Rule trading programs by state allocations. EPA is therefore requesting comment—in conjunction with comment on the alternative allocation methodologies—on both of the following two approaches, which are analogous to the approaches adopted under the CAIR trading programs. These approaches would allow states to—and would provide the only ways that states could—allocate allowances and participate in the proposed Transport Rule trading programs.

Under the first approach, EPA would adopt new provisions, as part of the proposed Transport Rule FIP that would allow a state to submit a SIP (referred as an abbreviated SIP) that would modify specified provisions of the proposed Transport Rule FIP trading programs. Specifically, the abbreviated SIP would substitute state allocation provisions (for entities other than opt-in units)—for control periods in years after 2012 and applicable to a proposed Transport Rule FIP trading program—in lieu of the current allocation provisions (except those for opt-in units) under those proposed Transport Rule FIP program. The Transport Rule FIP provisions that could be replaced would be proposed §§ 97.411(a) and (b) and 97.412 (in the proposed TR NO_X Annual Trading Program), proposed §§ 97.511(a) and (b) and 97.512 (in the TR NO_X Ozone Season Trading Program), proposed §§ 97.611(a) and (b) and 97.612 (in the TR SO_2 Group 1 Trading Program), and proposed §§ 97.711(a) and (b) and 97.712 (in the TR SO_2 Group 2 Trading Program). The abbreviated SIP could provide for this substitution of state allocations in one or more of the proposed Transport Rule FIP trading programs applicable to the state.

If the state allocation provisions met certain requirements and the abbreviated SIP did not change any other provisions in the respective proposed Transport Rule FIP trading program, then EPA would approve the abbreviated SIP. In the substitute state allocation provisions, the state could allocate allowances to Transport Rule units (whether existing or new units) or other entities (such as renewable energy facilities) or could auction some or all of the allowances. For EPA approval, the state allocation provisions would have to meet the following requirements. First, the provisions would have to provide that, for each year for which the state allocation provisions would apply, the total amount of control period (annual or ozone season) allowances allocated and, where applicable, auctioned could not exceed the applicable state budget for that year under the relevant proposed Transport Rule FIP trading program.

Second, to the extent the state provisions would provide for allocations for, or auctions open to, existing units (*i.e.,* units covered by proposed § 97.411(a), § 97.511(a), 97.611(a), or 97.711(a), as applicable), the provisions would have to provide that the permitting authority under title V of the CAA for the state would issue final allocations and, if applicable, auction results by May 1 (or January 1 with regard to the NO_X ozone season program) of the year two years before the year of the control period for which the allowances would be distributed. To the extent the provisions would provide for allocations for or auctions open to new units (*i.e.,* units covered by proposed § 97.411(b) and 97.412, § 97.511(b) and 97.512, 97.611(b) and 97.612, or 97.711(b) and 97.712, as applicable) or any other entities, the provisions would also have to provide that the permitting authority would issue final allocations and, if applicable, auction results by August 1 (or May 1 with regard to the NO_X ozone season program) of the year of the control period for which the allowances would be distributed. The allocation (or auction) of allowances would be final and could not be subject to modification

(*e.g.,* through an allowance surrender adjusting the allocation).[6]

Third, the state provisions could not change any other provisions of the proposed Transport Rule FIP trading programs with regard to the allowances (*e.g.,* the deadlines for allocation recordation, requirements for transfer or use of allowances, and allocation and recordation of allowances for opt-in units) or any other aspect of such trading programs.[7]

Under the second approach, EPA would adopt a new rule that would provide that, if a state submitted a SIP (referred to as a full SIP) that adopted trading program regulations meeting certain requirements for control period in years after 2012, then EPA would approve the full SIP as correcting the deficiency under CAA section 110(a)(2)(D)(i)(I) in the state's SIP that was the basis for issuance of the comparable proposed Transport Rule FIP. In the state allocation provisions, the state could allocate allowances to Transport Rule units (whether existing or new units, except for opt-in units) or other entities (such as renewable energy facilities) or could auction allowances.

As a result of EPA approval of the state's full SIP under this second approach, the state's trading program set forth in the SIP would be integrated with the comparable proposed Transport Rule FIP trading program (whether or not modified by an abbreviated SIP) covering other states. Moreover, covered sources in the state could participate in the integrated trading program, and the allowances issued under the state trading program would be interchangeable with the allowances issued in the comparable proposed Transport Rule trading program.

Like the abbreviated SIP discussed above, a full SIP providing for state participation in the integrated trading program could include only limited differences from the provisions of the proposed Transport Rule FIP trading program. First, the only differences that the full SIP could adopt would be in the allocation provisions (other than those for opt-in units). Second, the revised state allocation provisions in the full SIP would have to meet the same requirements as state allocation provisions in an abbreviated SIP. For example, the full SIP would have to provide that, for each year, the total amount of control period (annual or ozone season) allocations would not exceed the applicable state budget for that year. Further, to the extent the full SIP would provide for allocations for existing units, the SIP would have to provide that the permitting authority would issue final allocations by May 1 (or January 1 with regard to the NO_X ozone season program) of the year two years before the year of the control period for which the allowances would be distributed. To the extent the full SIP would provide for allocations for new units or any other entities, the SIP would also have to provide that the permitting authority would issue final allocations by August 1 (or May 1 with regard to the NO_X ozone season program) of the year of the control period for which the allowances would be distributed. The allocation of allowances would be final and could not be subject to modification.[8]

It is important to note that, of course, each state would still have the ability to submit other types of SIPs using emissions reduction approaches other than the proposed Transport Rule trading programs to correct the deficiency under CAA section 110(a)(2)(D)(i)(I) in the state's SIP that was the basis for the proposed Transport Rule FIPs. The EPA would review such SIP submissions on a case-by-case basis and intends to provide guidance to states that want to develop and submit such SIPs. However, in order for the state to use the proposed Transport Rule trading programs to correct that deficiency in the SIP, the state would have to submit a full SIP in accordance with this second approach.

In order for a state's allocation provisions in an abbreviated SIP or a full SIP to replace EPA's allocation provisions for a control period in a given year under these two approaches, a state would have to submit the abbreviated SIP or full SIP meeting the requirements of these approaches by a deadline that would provide EPA sufficient time to review and approve the SIP provisions and to record the unit-by-unit allocations or auction results. EPA would need about 6 months—starting from the date of receipt of an abbreviated or full SIP—to complete its review and approval process, which would have to provide an opportunity for public comment on the approval (or disapproval) action. The following tables show, for the allocations or auction results for the control periods in 2012 through 2018, the deadlines that would apply for submission of an abbreviated or full SIP, for submission of the unit-by-unit allocations or auction results for recordation by EPA, and for recordation. These tables assume: Allocation (or auction) and recordation of allowances for existing units under the Transport Rule trading programs one year at a time and about one and one-half years ahead of the year for which the allocations (or auctions) apply; and allocation (or auction) and recordation of allowances for new units and other entities one year at a time and six months after the commencement of the control period for which the allocations (or auction) apply. Because EPA anticipates issuing the final Transport Rule around mid-2011, there would not be sufficient time for states to develop and submit abbreviated or full SIPs with allowance allocation provisions, and for EPA to review and approve such SIP submissions, before September 2011 when EPA would record allocations to existing units for 2012 and 2013. Consequently, the tables assume that the first year for which state allocations might be used, in lieu of EPA allocation, would be 2014.

TABLE III—DEADLINES FOR SUBMISSION OF ABBREVIATED OR FULL SIPS AND UNIT-BY-UNIT ALLOCATIONS OR AUCTION RESULTS AND FOR RECORDATION; ANNUAL TRADING PROGRAMS

First TR control period for which allowances would be allocated or auctioned	Deadline for State submitting abbreviated or full SIP	Deadline for State submitting allocations or auction results for existing units	Deadline for State submitting allocations or auction results for new units and others	Deadline for EPA recording allocations or auction results for existing units	Deadline for EPA recording allocations or auction results for new units and others
2012	NA	NA	NA	September 1, 2011	September 1, 2012.
2013	NA	NA	NA	September 1, 2011	September 1, 2013.

[6] If any auctions were to be conducted, the provisions would have to specify the auction procedures that the permitting authority would use.

[7] However, if auctions were to be conducted, the abbreviated SIP would have to provide that any allowance auctioned to a covered unit or source would be treated as an allocated allowance, solely for purposes of applying the assurance provisions in the proposed Transport Rule FIP.

[8] In addition, the requirements for state allocation provisions in full SIPs would apply to any auctioned allowances in the same way that is described above with regard to any allowances to be auctioned under abbreviated SIPs.

TABLE III—DEADLINES FOR SUBMISSION OF ABBREVIATED OR FULL SIPS AND UNIT-BY-UNIT ALLOCATIONS OR AUCTION RESULTS AND FOR RECORDATION; ANNUAL TRADING PROGRAMS—Continued

First TR control period for which allowances would be allocated or auctioned	Deadline for State submitting abbreviated or full SIP	Deadline for State submitting allocations or auction results for existing units	Deadline for State submitting allocations or auction results for new units and others	Deadline for EPA recording allocations or auction results for existing units	Deadline for EPA recording allocations or auction results for new units and others
2014	November 1, 2011	May 1, 2012	August 1, 2014	June 1, 2012	September 1, 2014.
2015	November 1, 2012	May 1, 2013	August 1, 2015	June 1, 2013	September 1, 2015.
2016	November 1, 2012	May 1, 2014	August 1, 2016	June 1, 2014	September 1, 2016.
2017	November 1, 2014	May 1, 2015	August 1, 2017	June 1, 2015	September 1, 2017.
2018	November 1, 2015	May 1, 2016	August 1, 2018	June 1, 2016	September 1, 2018.

TABLE IV—DEADLINES FOR SUBMISSION OF ABBREVIATED OR FULL SIPS AND UNIT-BY-UNIT ALLOCATIONS OR AUCTION RESULTS AND FOR RECORDATION; OZONE SEASON TRADING PROGRAMS

First TR control period for which allowances would be allocated or auctioned	Deadline for State submitting abbreviated or full SIP	Deadline for State submitting allocations or auction results for existing units	Deadline for State submitting allocations or auction results for new units and others	Deadline for EPA recording allocations or auction results for existing units	Deadline for EPA recording allocations or auction results for new units and others
2012	NA	NA	NA	September 1, 2011	June 1, 2012.
2013	NA	NA	NA	September 1, 2011	June 1, 2013.
2014	November 1, 2011	May 1, 2012	May 1, 2014	June 1, 2012	June 1, 2014.
2015	November 1, 2012	May 1, 2013	May 1, 2015	June 1, 2013	June 1, 2015.
2016	November 1, 2013	May 1, 2014	May 1, 2016	June 1, 2014	June 1, 2016.
2017	November 1, 2014	May 1, 2015	May 1, 2017	June 1, 2015	June 1, 2017.
2018	November 1, 2015	May 1, 2016	May 1, 2018	June 1, 2016	June 1, 2018.

As discussed above, a trading program adopted by a state in a full SIP and approved by EPA under the second approach would be fully integrated with any comparable proposed Transport Rule FIP trading program (*i.e.,* the proposed TR NO_X Annual, TR NO_X Ozone Season, TR SO_2 Group 1, or TR SO_2 Group 2 Trading Program respectively) for other states. This would apply whether the comparable proposed Transport Rule FIP program for other states was modified by an abbreviated SIP approved by EPA under the first approach or was not modified by an abbreviated SIP. The integration of these three types of trading programs would be accomplished primarily through the definitions of the terms, "TR NO_X Annual allowance", "TR NO_X Ozone Season allowancerdquo;, "TR SO_2 Group 1 allowance", and "TR SO_2 Group 2 allowance" in the full SIPs approved by EPA and the proposed TR FIP trading programs (whether or not the programs were modified by abbreviated SIPs). "TR NO_X Annual allowance" would be defined in the state and proposed Transport Rule FIP trading programs as including allowances issued under any of the following trading programs: The comparable EPA-approved state trading programs; the comparable proposed Transport Rule FIP trading program with EPA-approved state allocation provisions; and the proposed Transport Rule FIP trading program with EPA allocation provisions. Similarly, the definitions in the state and Transport Rule FIP trading programs of "TR NO_X Ozone Season allowance", "TR SO_2 Group 1 allowance", and "TR SO_2 Group 2 allowance" respectively would include allowances issued under all three types of trading programs. As a result, allowances issued in one approved state trading program would be interchangeable with allowances issued in the comparable Transport Rule FIP trading program (whether or not modified by an abbreviated SIP), and all these allowances could be used for compliance with the allowance-holding requirements (to cover emissions and to meet assurance provision requirements) in all three types of trading programs.

The integration of state and the proposed Transport Rule FIP trading programs would also be reflected in the definitions of "TR NO_X Annual Trading Program," "TR NO_X Ozone Season Trading Program", "TR SO_2 Group 1 Trading Program", and "TR SO_2 Group 2 Trading Program". Each of these definitions in the state and Transport Rule FIP trading programs would expressly encompass the comparable proposed Transport Rule FIP trading programs (whether or not modified by an abbreviated SIP) and the comparable EPA-approved state full SIP trading program.

Dated: December 30, 2010.

Brian McLean,

Director, Office of Atmospheric Programs.

[FR Doc. 2011–109 Filed 1–6–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA–2010–0003; Internal Agency Docket No. FEMA–B–1170]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule.

SUMMARY: Comments are requested on the proposed Base (1% annual-chance) Flood Elevations (BFEs) and proposed BFE modifications for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the proposed regulatory flood elevations for the reach described by the downstream and upstream locations in the table below. The BFEs and modified BFEs are a part of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to

qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, these elevations, once finalized, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents in those buildings.

DATES: Comments are to be submitted on or before April 7, 2011.

ADDRESSES: The corresponding preliminary Flood Insurance Rate Map (FIRM) for the proposed BFEs for each community is available for inspection at the community's map repository. The respective addresses are listed in the table below.

You may submit comments, identified by Docket No. FEMA–B–1170, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) *luis.rodriguez1@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings.

Comments on any aspect of the Flood Insurance Study and FIRM, other than the proposed BFEs, will be considered. A letter acknowledging receipt of any comments will not be sent.

National Environmental Policy Act. This proposed rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. An environmental impact assessment has not been prepared.

Regulatory Flexibility Act. As flood elevation determinations are not within the scope of the Regulatory Flexibility Act, 5 U.S.C. 601–612, a regulatory flexibility analysis is not required.

Executive Order 12866, Regulatory Planning and Review. This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866, as amended.

Executive Order 13132, Federalism. This proposed rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This proposed rule meets the applicable standards of Executive Order 12988.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Redwood County, Minnesota, and Incorporated Areas				
Cottonwood River	Approximately 0.93 mile downstream of U.S. Route 71.	None	+1,042	City of Sanborn, Unincorporated Areas of Redwood County
	Approximately 2.1 miles upstream of County Road 57	None	+1,105	
Crow Creek	Approximately 900 feet downstream of Minnesota Prairie Railroad.	None	+840	City of Redwood Falls, Unincorporated Areas of Redwood County.
	Approximately 0.45 mile upstream of County Highway 1.	None	+1,009	
Minnesota River	Approximately 2.54 miles downstream of County Highway 11.	+823	+825	City of Redwood Falls, Unincorporated Areas of Redwood County.
	Approximately 1.09 miles upstream of County Highway 7.	+874	+877	
Ramsey Creek	At the Redwood River confluence	None	+884	City of Redwood Falls, Unincorporated Areas of Redwood County.
	Approximately 245 feet upstream of Kenwood Avenue	None	+1,016	

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Redwood River	At the Minnesota River confluence	+842	+843	City of Redwood Falls, City of Seaforth, City of Vesta, Unincorporated Areas of Redwood County.
	Approximately 0.88 mile upstream of County Road 51	None	+1,067	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.
** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Redwood Falls
Maps are available for inspection at 333 South Washington Street, Redwood Falls, MN 56283.

City of Sanborn
Maps are available for inspection at 171 North Main Street, Sanborn, MN 56083.

City of Seaforth
Maps are available for inspection at 205 Oak Street, Seaforth, MN 56287.

City of Vesta
Maps are available for inspection at 150 Front Street West, Vesta, MN 56292.

Unincorporated Areas of Redwood County
Maps are available for inspection at 403 South Mill Street, Redwood Falls, MN 56283.

Clark County, Missouri, and Incorporated Areas

Big Branch (backwater effects from Mississippi River).	From the Honey Creek confluence to approximately 0.5 mile downstream of State Highway H.	None	+497	Unincorporated Areas of Clark County.
Buck Run (overflow effects from Mississippi River).	At the Lewis County boundary	+496	+495	Unincorporated Areas of Clark County.
	Approximately 0.6 mile downstream of Avenue of the Saints.	None	+496	
Doe Run (backwater effects from Mississippi River).	From the Lewis County boundary to approximately 1,290 feet downstream of Avenue of the Saints.	None	+496	Unincorporated Areas of Clark County.
Mississippi River	Approximately 2.5 miles downstream of the Fox River confluence.	+496	+495	City of Alexandria, Unincorporated Areas of Clark County.
	At the Des Moines River confluence	+500	+499	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.
** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Alexandria
Maps are available for inspection at the Community Center, 109 Market Street, Alexandria, MO 63430.

Unincorporated Areas of Clark County
Maps are available for inspection at the Clark County Courthouse, 111 East Court Street, Suite 4, Kahoka, MO 63445.

Lewis County, Missouri, and Incorporated Areas

Artesian Branch (backwater effects from Mississippi River).	From approximately 1,000 feet downstream of the Artesian Branch Tributary 1 confluence to approximately 270 feet downstream of U.S. Route 61.	None	+493	Unincorporated Areas of Lewis County.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Artesian Branch Tributary 1 (backwater water effects from Mississippi River).	From the Artesian Branch confluence to approximately 240 feet downstream of U.S. Route 61.	None	+493	Unincorporated Areas of Lewis County.
Doe Run (overflow effects from Mississippi River).	Approximately 475 feet downstream of the Doe Run Tributary 4 confluence.	None	+494	Unincorporated Areas of Lewis County.
	Approximately 1.0 mile upstream of County Road 494	None	+495	
Doe Run Tributary 4 (backwater effects from Mississippi River).	From the Doe Run confluence to approximately 360 feet downstream of U.S. Route 61.	None	+494	Unincorporated Areas of Lewis County.
Durgens Creek (backwater effects from Mississippi River).	From the Mississippi River confluence to approximately 0.4 mile downstream of U.S. Route 61.	None	+488	Unincorporated Areas of Lewis County.
Mississippi River	Approximately 3.0 miles downstream of the Durgens Creek confluence.	None	+487	City of Canton, City of La Grange, Unincorporated Areas of Lewis County.
	At the Clark County boundary	None	+495	
Oyster Branch (backwater effects from Mississippi River).	From the Mississippi River confluence to approximately 630 feet downstream of U.S. Route 61 Business.	None	+489	Unincorporated Areas of Lewis County.
Wyaconda River (backwater effects from Mississippi River).	From the Mississippi River confluence to approximately 410 feet upstream of U.S. Route 61 Business.	None	+489	City of La Grange, Unincorporated Areas of Lewis County.

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Canton
Maps are available for inspection at City Hall, 106 North 5th Street, Canton, MO 63435.

City of La Grange
Maps are available for inspection at City Hall, 118 South Main Street, La Grange, MO 63448.

Unincorporated Areas of Lewis County
Maps are available for inspection at the Lewis County Courthouse, 100 East Lafayette Street, Monticello, MO 63457.

Madison County, Missouri, and Incorporated Areas

Tollar Branch	Approximately 775 feet downstream of Marvin Avenue.	+738	+740	Village of Cobalt.
	Approximately 1,310 feet upstream of Mine LaMotte Street.	None	+788	
Village Creek	At the upstream side of Catherine Mine Road	+708	+707	City of Junction City.
	Approximately 550 feet upstream of Catherine Mine Road.	None	+710	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Junction City
Maps are available for inspection at 1 Court Square, Fredericktown, MO 63645.

Village of Cobalt
Maps are available for inspection at 1 Court Square, Fredericktown, MO 63645.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	
Taylor County, Texas, and Incorporated Areas				
Elm Creek	Just west of the intersection of Impact Drive and Clinton Street.	None	+1,668	Town of Impact, Unincorporated Areas of Taylor County.
	Approximately 717 feet northeast of the intersection of Impact Drive and FM Road 2404.	None	+1,673	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

Town of Impact
Maps are available for inspection at 555 Walnut Street, Abilene, TX 79602.

Unincorporated Areas of Taylor County
Maps are available for inspection at 400 Oak Street, Suite 107, Abilene, TX 79602.

Snohomish County, Washington, and Incorporated Areas				
Haskel Slough	Approximately 0.7 mile downstream of State Highway 203.	None	+56	Unincorporated Areas of Snohomish County.
	Approximately 1.4 miles upstream of State Highway 203.	None	+67	
North Fork Skykomish River	Approximately 308 feet upstream of the South Fork Skykomish River confluence.	+465	+461	Town of Index, Unincorporated Areas of Snohomish County.
	Approximately 2.7 miles upstream of 5th Street	+675	+673	
Riley Slough	Approximately 1.2 miles upstream of the Snoqualmie River confluence.	None	+49	Unincorporated Areas of Snohomish County.
	Approximately 2.2 miles upstream of State Highway 203.	None	+72	
Skykomish River	Approximately 4.6 miles downstream of Mann Road	+91	+90	City of Gold Bar, City of Sultan, Unincorporated Areas of Snohomish County.
	Approximately 216 feet downstream of Burlington Northern Santa Fe Railway.	+359	+351	
Snohomish River	Approximately 528 feet downstream of the Marshland Diversion Channel confluence (Storage Area #2).	+27	+26	City of Monroe, City of Snohomish, Unincorporated Areas of Snohomish County.
	Approximately 0.5 mile downstream of State Highway 9 (Storage Area #4).	+28	+29	
Sultan River	At the upstream side of State Highway 2	+118	+117	City of Sultan, Unincorporated Areas of Snohomish County.
	Approximately 3.2 miles upstream of State Highway 2	+180	+183	

* National Geodetic Vertical Datum.
+ North American Vertical Datum.
# Depth in feet above ground.
∧ Mean Sea Level, rounded to the nearest 0.1 meter.

** BFEs to be changed include the listed downstream and upstream BFEs, and include BFEs located on the stream reach between the referenced locations above. Please refer to the revised Flood Insurance Rate Map located at the community map repository (see below) for exact locations of all BFEs to be changed.

Send comments to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472.

ADDRESSES

City of Gold Bar
Maps are available for inspection at 107 5th Street, Gold Bar, WA 98251.

Flooding source(s)	Location of referenced elevation **	* Elevation in feet (NGVD) + Elevation in feet (NAVD) # Depth in feet above ground ∧ Elevation in meters (MSL)		Communities affected
		Effective	Modified	

City of Monroe
Maps are available for inspection at 806 West Main Street, Monroe, WA 98272.

City of Snohomish
Maps are available for inspection at 116 Union Avenue, Snohomish, WA 98290.

City of Sultan
Maps are available for inspection at 319 Main Street, Sultan, WA 98294.

Town of Index
Maps are available for inspection at 511 Avenue A, Index, WA 98256.

Unincorporated Areas of Snohomish County
Maps are available for inspection at 3000 Rockefeller Avenue, Everett, WA 98201.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: December 27, 2010.

Sandra K. Knight,

Deputy Federal Insurance and Mitigation Administrator, Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2011–132 Filed 1–6–11; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 20

[PS Docket No. 07–114; WC Docket No. 05–196; FCC 10–177; DA 10–2267]

Wireless E911 Location Accuracy Requirements; E911 Requirements for IP–Enabled Service Providers

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment and reply comment dates.

SUMMARY: The order provides notice that the comment period cycle for the Commission's Further Notice of Proposed Rulemaking (FNPRM) and Notice of Inquiry (NOI) has been extended to provide interested parties a meaningful opportunity to file full and informed comment for a complete record concerning the numerous issues raised in the proceeding.

DATES: Submit comments on or before January 19, 2011. Submit reply comments on or before February 18, 2011.

ADDRESSES: You may submit comments, identified by PS Docket No. 07–114 and WC Docket No. 05–196, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Federal Communications Commission's Web Site: *http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments on the Commission's Electronic Comment Filing System (ECFS).
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the FPRM and NOI, Section V., Procedural Matters, in this proceeding.

FOR FURTHER INFORMATION CONTACT: Patrick Donovan, Public Safety and Homeland Security Bureau, at (202) 418–2413, Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554; or via the Internet to *Patrick.Donovan@fcc.gov.*

SUPPLEMENTARY INFORMATION: 1. On September 23, 2010, the Federal Communications Commission adopted an FNPRM and NOI, seeking comment on how to further improve the location capability of 911 and E911 services for existing and new voice communications technologies, including new broadband technologies associated with the deployment of Next Generation 911 (NG911) networks. The E911 Location Accuracy FNPRM and NOI was published in the **Federal Register** on November 2, 2010, 75 FR 67321. Thus, comments submitted in response to the E911 Location Accuracy FNPRM and NOI must be filed on or before January 3, 2011; and reply comments must be filed on or before January 31, 2011.

2. On November 22, 2010, the Association of Public-Safety Communications Officials—International (APCO), the National Emergency Number Association (NENA), the National Association of State 911 Administrators (NASNA), CTIA—The Wireless Association (CTIA), and the Telecommunications Industry Association (TIA) (collectively, the "Parties") jointly filed a request to extend the comment and reply comment deadlines in this proceeding until January 19, 2011, and February 18, 2011, respectively. The parties argue that "[a] short-term extension is in the public interest to allow interested parties to meaningfully address the issues raised in this proceeding."

3. We grant the parties' request for extension of time to file comments and reply comments. Generally, it is the policy of the Commission that extensions of time are not routinely granted. Nevertheless, the Commission has previously found that an extension of time is warranted when such an extension is necessary to ensure that the Commission receives full and informed responses and that affected parties have a meaningful opportunity to develop a complete record for the Commission's consideration. In light of the multitude of issues that the Commission seeks comment upon in the E911 Location Accuracy FNPRM and NOI, we find that an extension is warranted to ensure that all interested parties have the time necessary to prepare full and informed comments and reply comments.

4. Additionally, we concur with the Parties that granting an extension of time would permit various Communications Security, Reliability and Interoperability Council (CSRIC) working groups to develop and finalize recommendations relating to E911 and NG911. As the Parties noted, "[m]any of those working group members plan to file comments and/or reply comments in this proceeding." Indeed, in the E911 Location Accuracy FNPRM and NOI, the Commission highlighted the

significance of CSRIC's contribution to this proceeding. Under these circumstances, the Bureau finds that the proposed extension of time will provide CSRIC working group members with the time to develop thorough recommendations for the CSRIC and meaningful comments in this proceeding.

5. Accordingly, *It is ordered* that, pursuant to sections 4(i), 4(j), and 5(c) of the Communications Act, 47 U.S.C. 154(i), 154(j), 155(c), and sections 0.191, 0.392, and 1.46 of the Commission's rules, 47 CFR 0.191, 0.392, 1.46, the Joint Request for Extension of Comment and Reply Comment Deadlines filed by the Association of Public-Safety Communications Officials—International, the National Emergency Number Association, the National Association of State 911 Administrators, CTIA—The Wireless Association, and the Telecommunications Industry Association, Is Granted.

Federal Communications Commission.

Thomas J. Beers,

Chief, Policy Division, Public Safety and Homeland Security Bureau.

[FR Doc. 2011–121 Filed 1–6–11; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 76, No. 5
Friday, January 7, 2011

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 3, 2011.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Office of the Assistant Secretary for Administration

Title: USDA Race, Ethnicity and Gender Data Collection.

OMB Control Number: 0503–NEW.

Summary of Collection: Section 14006 and 14007 of the Food, Conservation, and Energy Act of 2008, 7 U.S.C. 8701 (referred to as the 2008 Farm Bill) establishes a requirement for the Department of Agriculture (USDA) to annually compile application and participation rate data regarding socially disadvantaged farmers or ranchers by computing for each program of the USDA that serves agriculture producers and landowners (a) raw numbers of applicants and participants by race, ethnicity, and gender, subject to appropriate privacy protection, as determined by the Secretary; and (b) the application and participation rate, by race, ethnicity and gender as a percentage of the total participation rate of all agricultural producers and landowners for each county and State in the United States.

Need and Use of the Information: Data will be collected on a voluntary basis through a questionnaire to determine the race, ethnicity and gender of farmers and ranchers who apply for and who participate in USDA programs and services. The data will enable the Secretary and the Office of Advocacy and Outreach and the agencies' outreach offices in reaching current and prospective socially disadvantaged farmers or ranchers in a linguistically appropriate manner to focus resources in a particular county or region where low participation is indicated by the data to improve the participation of those farmers and ranchers in USDA programs. This is not a random sampling and is in no way considered to be a statistically significant analysis. The data is intended to be used as one indicator in targeting and designing outreach activities and in assessing compliance with civil rights laws in program delivery. The data may also be used as an indicator in directing compliance reviews to geographic areas where there are indications of low participation in USDA programs by minorities and women, thus serving as an "early warning system" that warrants further investigations. Failure to collect this information will have a negative impact on USDA's outreach activities and could result in an inability of the agencies to equitably deliver programs and services to applicant and producers.

Description of Respondents: Individuals or households.

Number of Respondents: 3,200,000.

Frequency of Responses: Reporting: Other (once).

Total Burden Hours: 106,667.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2011–80 Filed 1–6–11; 8:45 am]

BILLING CODE 3410–96–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 3, 2011.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Forest Service

Title: Trends in Use and Users in the Boundary Waters Canoe Area Wilderness, Minnesota.

OMB Control Number: 0596–0208.

Summary of Collection: The Wilderness Act of 1964, Public Law 88–577 (Act) directs the National Wilderness Preservation System (System) be managed to preserve natural conditions and to provide outstanding opportunities for solitude or a primitive and unconfined type of recreation. The System administers wilderness for the use and enjoyment of the American people in such manner as will leave these areas unimpaired for future use and enjoyment as wilderness. The Act encourages the gathering and dissemination of information regarding the use and enjoyment of these areas as wilderness.

Need and Use of the Information: The data collected from this information collection request will update trend information for the Boundary Waters Canoe Area Wilderness in Minnesota. Mangers of this Wilderness need to know and be able to inform the public, how visits (and visitors) have changed because of changing policies; natural disturbances; and national, regional, and local societal changes in 1990's and early 21st century. Mangers use this information to adapt current programs to changing societal interests and needs.

Description of Respondents: Individuals or households.

Number of Respondents: 500.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 167.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2011–81 Filed 1–6–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Evaluation of the Impact of the Summer Food Service Programs Enhancement Demonstrations on Food Insecurity

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a new collection for the purpose of conducting The Evaluation of the Impact of the Summer Food Service Programs Enhancement Demonstrations on Food Insecurity.

DATES: Written comments must be received on or before March 8, 2011.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Steven Carlson, Director, Office of Research and Analysis, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Steven Carlson at 703–305–2576 or via e-mail to *Steven.Carlson@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Steven Carlson at 703–305–2017.

SUPPLEMENTARY INFORMATION:

Title: Evaluation of the Impact of the Summer Food Service Programs Enhancement Demonstrations on Food Insecurity.

Form Number: Not yet assigned.

OMB Number: 0584–NEW.

Expiration Date: Not yet assigned.

Type of Request: New Collection of Information.

Abstract: The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 2010 (Pub. L. 111–80), Section 749(g), directed that the Secretary of Agriculture shall carry out demonstration projects to develop and test methods of providing access to food for children in urban and rural areas during the summer months when schools are not in regular session to reduce or eliminate the food insecurity and hunger of children and to improve the nutritional status of children. Demonstrations of enhancements to existing Summer Food Service Programs (SFSP) will carry out the demonstration projects Congress directed USDA to perform in this section.[1] These demonstrations will include the Home Delivery Demonstration and the Food Backpack Demonstration. The Home Delivery Demonstration will offer breakfast and lunch delivery to the homes of eligible children in rural areas. This demonstration will only operate in rural areas, and only children identified by school districts as eligible for free and reduced-price school meals will be eligible to receive delivered meals. Children, age 18 and younger, normally eligible to receive meals at SFSP sites, will be eligible to receive weekend and holiday meals under the Food Backpack Demonstration Project. In addition, the Act directed the Secretary of Agriculture to provide for an independent evaluation of the demonstration projects using rigorous methodologies. The Evaluation of the Impact of the Summer Food Service Programs Enhancement Demonstrations on Food Insecurity will carry out the provisions of the Act.

The evaluation of these projects is intended to provide policymakers with clear, rigorous and timely findings to make decisions about potential changes to Federal summer feeding programs during the next Child Nutrition reauthorization cycle. Primarily, the

[1] USDA is also conducting demonstrations of Summer Electronic Benefits for Children Household-Based demonstrations. Those demonstrations are not part of this Information Collection.

evaluation will examine the impact of the demonstration activities on program operations, benefit usage within target households, and food security. In addition to impact measures, the evaluation will document the process and challenges of implementing the demonstrations. The results will provide valuable information should the demonstration succeed and could lead to policy changes. The evaluation will gather data through surveys from sampled eligible households during the summer and fall of 2011. A third and final household survey will be conducted in summer 2012. In the demonstration areas, roughly the same number of households with eligible children will be sampled from each of two primary strata: treatment group (participating children who have signed up for the summer food program prior to the summer break) and control group (nonparticipating children).

Affected Public: Individuals/Households; State, Local and Tribal Government. State or tribal agencies, usually departments of education or health, oversee the administration of the SFSP which is most frequently conducted by local government, particularly local education authorities.

Respondent Type: the parents/guardians of individual school-aged children in each demonstration area; and State and local agency officials in each demonstration area.

Estimated Number of Respondents: The maximum total estimated number of respondents, assuming a 100% response rate, is 6,320 (3,160 in 2011 and 3,160 in 2012). Over both years this includes: 1,580 treatment and 1,580 control parents/guardians (1 per interviewed household) in each year; and 100 State and local agency officials in each year.

Estimated Number of Responses per Respondent: There will be one interview per parent/guardian and 1 per State or local official.

Estimated Total Annual Responses: 3,260.

Estimated Time per Response: The estimated average response time is 60 minutes (1 hour), as shown in the table below.

Estimated Total Annual Burden on Respondents: The maximum total estimated response time is 3,260 hours in 2011 and 3,260 hours in 2012. See the table below for estimated total annual burden for each type of respondent.

Type of respondent	Respondent type	Type of instrument	Number of respondents (annual)	Frequency of response	Estimated annual responses	Time per respondent	Annual burden hours
Individual/Households.	Parent-Guardian	Interviews	3,160	1	3,160	1	3,160
State and Local ..	State and Local Agency Official.	Interviews	100	1	100	1	100
Total Annual Cost to Respondents.	.....	.....	3,260	.....	3,260	.....	3,260

Dated: December 23, 2010.

Julia Paradis,

Administrator, Food and Nutrition Service.

[FR Doc. 2011–106 Filed 1–6–11; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Prince William Sound Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Prince William Sound Resource Advisory Committee will meet in Cordova, Alaska. The committee is meeting as authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110–343) and in compliance with the Federal Advisory Committee Act. The purpose of the meeting is to review, discuss and select projects to be funded thru the Secure Rural Schools Act.

DATES: The meeting will be held January 14th and 15th, starting at 9 a.m.

ADDRESSES: The meeting will be held upstairs of the Moose Lodge on 2nd Street. Written comments should be sent to Teresa Benson, P.O. Box 280, Cordova, AK 99574. Comments may also be sent via e-mail to *tbenson@fs.fed.us,* or via facsimile to (907) 424–7214.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Cordova Ranger District (612 2nd Street, Cordova, AK) or the Glacier Ranger District (145 Forest Station Road, Girdwood, AK).

FOR FURTHER INFORMATION CONTACT: Teresa Benson, Designated Federal Official, c/o USDA Forest Service, P.O. Box 280, Cordova, Alaska 99574, telephone (907) 424–4742.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. The following business will be conducted: The Prince William Sound Resource Advisory Committee (RAC) will be discussing and voting on proposals that have been received from communities of the Prince William Sound. The proposals that may receive funding would enhance forest ecosystems or restore and improve land health and water quality on the Chugach National Forest and other near-by lands including the communities of Chenega, Cordova, Tatitlek, Valdez and Whittier. The RAC is responsible for approving projects with funds made available from years 2008–2012.

The public is welcome to attend the January 14–15 RAC meeting. Committee discussion is limited to Forest Service staff and Committee members. However, public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Persons who wish to bring related matters to the attention of the Committee may file written statements with the Committee staff before or after the meeting. Public input sessions will be provided and individuals who made written requests by January 12th will have the opportunity to address the Committee at those sessions.

Dated: December 21, 2010.

Teresa M. Benson,

District Ranger.

[FR Doc. 2011–23 Filed 1–6–11; 8:45 am]

BILLING CODE 3410–11–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

In connection with its investigation into an explosion and fire that occurred at the Bayer CropScience facility in Institute, West Virginia, on August 28, 2008, the U.S. Chemical Safety Board (CSB) announces that it will hold a public meeting on January 20, 2011, in Institute, West Virginia, to present the findings from its investigation of the explosion that fatally injured two workers.

The meeting will begin at 6:30 p.m. at the West Virginia State University Wilson Building, Multipurpose Room, 103 University Union, Institute, WV, 25112. The meeting is free and open to the public. Pre-registration is not required, but to assure adequate seating, attendees are encouraged to pre-register by emailing their names and affiliations to *publicmeeting@csb.gov* by January 15th.

At the meeting CSB staff will present to the Board the results of their investigation into this incident. Key issues involved in the investigation concern process hazards analysis and pre-startup safety review; operating procedures, operator training, emergency planning and response. Following the presentation of the CSB's findings and safety recommendations, a panel of outside witnesses will be invited to speak on a number of issues related to the investigation findings and the board's recommendations. This will then be followed by a public comment period prior to a Board vote on the report.

Following the staff presentation, panel comments, and the conclusion of the public comment period, the Board will consider whether to approve the final report and recommendations. All staff presentations are preliminary and are intended solely to allow the Board to consider in a public forum the issues and factors involved in this case. No factual analyses, conclusions or findings presented by staff should be considered final. Only after the Board has considered the final staff presentation, listened to the witnesses and the public comments and approved the staff report will there be an approved final record of this incident.

Please notify CSB if a translator or interpreter is needed, at least 5 business days prior to the public meeting. For more information, please contact the Chemical Safety and Hazard Investigation Board at (202) 261–7600, or visit our Web site at: *http://www.csb.gov.*

Christopher W. Warner,

General Counsel.

[FR Doc. 2011–223 Filed 1–5–11; 4:15 pm]

BILLING CODE 6350–01–P

DEPARTMENT OF COMMERCE

U.S. Census Bureau

Proposed Information Collection; Comment Request; Monthly Retail Trade Survey

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, written comments must be submitted on or before March 8, 2011.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Timothy Winters, U. S. Census Bureau, Room 8K181, 4600 Silver Hill Road, Washington, DC 20233–6500, (301) 763–2713.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Monthly Retail Trade Survey provides estimates of monthly retail sales, end-of-month merchandise inventories, and quarterly e-commerce sales of retailers in the United States by selected kinds of business. Also, it provides monthly sales of food service establishments. The Bureau of Economic Analysis (BEA) uses this information to prepare the National Income and Products Accounts and to benchmark the annual input-output tables. Statistics provided from the Monthly Retail Trade Survey are used to calculate the gross domestic product (GDP).

Estimates produced from the Monthly Retail Trade Survey are based on a probability sample. The sample design consists of one fixed panel where all cases are requested to report sales, e-commerce sales, and/or inventories each month. The sample, consisting of about 12,000 retail businesses, is drawn from the Business Register, which contains all Employer Identification Numbers (EINs) and listed establishment locations. The sample is updated quarterly to reflect employer business "births" and "deaths"; adding new employer businesses identified in the Business and Professional Classification Survey and deleting firms and EINs when it is determined they are no longer active.

Listed below are the series of retail form numbers and a description of each form:

Series	Description
SM–44(06)S	Non Department Store/Sales Only/WO E-Commerce.
SM–44(06)SE	Non Department Store/Sales Only W E-Commerce.
SM–44(06)SS	Non Department Store/Sales Only/Screener.
SM–44(06)B	Non Department Store/Sales and Inventory/WO E-Comm.
SM–44(06)BE	Non Department Store/Sales and Inventory/W E-Comm.
SM–44(06)BS	Non Department Store/Sales and Inventory/Screener.
SM–45(06)S	Department Store/Sales Only/WO E-Commerce.
SM–45(06)SE	Department Store/Sales Only/W E-Commerce.
SM–45(06)SS	Department Store/Sales Only/Screener.
SM–45(06)B	Department Store/Sales and Inventory/WO E-Commerce.
SM–45(06)BE	Department Store/Sales and Inventory/W E-Commerce.
SM–45(06)BS	Department Store/Sales and Inventory/Screener.
SM–72(06)S	Food Services/Sales Only/WO E-Commerce.
SM–20(06)I	Non Department and Department Store/Inventory Only.

II. Method of Collection

We collect this information by mail, fax, and telephone follow-up.

III. Data

OMB Number: 0607–0717.

Form Number: SM–44(06)S, SM–44(06)SE, SM–44(06)SS, SM–44(06)B, SM–44(06)BE, SM–44(06)BS, SM–45(06)S, SM–45(06)SE, SM–45(06)SS, SM–45(06)B, SM–45(06)BE, SM–45(06)BS, SM–72(06)S, and SM–20(06)I.

Type of Review: Regular submission.

Affected Public: Retail and Food Services firms in the United States.

Estimated Number of Respondents: 10,000.

Estimated Time per Response: 7 minutes.

Estimated Total Annual Burden Hours: 14,000.

Estimated Total Annual Cost: The cost to the respondents for fiscal year 2010 is estimated to be $406,140.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Section 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 3, 2011.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2011–67 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 1–2011]

Foreign-Trade Zone 153—San Diego, CA; Application for Reorganization Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the City of San Diego, grantee of FTZ 153, requesting authority to reorganize and expand the zone under the alternative site framework (ASF) adopted by the Board (74 FR 1170, 1/12/09 (correction 74 FR 3987, 1/22/09); 75 FR 71069–71070, 11/22/10). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 3, 2011.

FTZ 153 was approved by the Board on October 14, 1988 (Board Order 394, 53 FR 41616, 10/24/88) and expanded on December 16, 1991 (Board Order 548, 56 FR 2160, 01/22/91 and on August 23, 2002 (Board Order 1245, 67 FR 56983, 09/06/02).

The current zone project includes the following sites: *Site 1* (316 acres)—Brown Field, Otay Mesa Road and Heritage Road, San Diego; *Site 2* (73 acres)—San Diego Business Park, Airway Road and State Road 125, San Diego; *Site 3* (60 acres)—Gateway Park, Harvest Road and Customs House Plaza Road, San Diego; *Site 4* (71 acres)—Britannia Commerce Center, Siempre Viva Road and Britannia Boulevard; *Site 5* (312 acres)—De La Fuente Business Park, Airway Road and Media Road, San Diego; *Site 6* (160 acres)—Brown Field Business Park, Otay Mesa Road and Britannia Boulevard; *Site 7* (389 acres)—Otay Mesa International Center, Harvest Road and Airway Road, San Diego; *Site 8* (86 acres)—Ocean View Hills Corporate Center, Otay Mesa Road and Innovative Drive, San Diego; *Site 9* (119 acres)—Siempre Viva Business Park, La Media Road and Siempre Viva Road, San Diego; *Site 10* (65 acres)—Brown Field Technology Park, southeast of the intersection of Otay Mesa Road and Britannia Boulevard; and, *Site 14* (0.51 acres)—Hoon Import & Export Inc., 2155 Britannia Boulevard, San Diego (expires 09/30/11).

The grantee's proposed service area under the ASF would be San Diego County and a portion of Riverside County, California, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The proposed service area is within and adjacent to the San Diego U.S. Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone project to include existing Sites 1 thru 10 as "magnet" sites and existing Site 14 as a "usage-driven site. The ASF allows for the possible exemption of one magnet site from the "sunset" time limits that generally apply to sites under the ASF, and the applicant proposes that Site 1 be so exempted. The applicant is also requesting approval of the following initial "usage-driven" sites: *Proposed Site 11* (54.18 acres)—Abbott Cardiovascular Systems Inc., 26531 Ynez Road, Temecula (Riverside County); *Proposed Site 12* (8.3 acres)—Abbot Cardiovascular Systems Inc., 42301 Zevo Drive, Temecula (Riverside County); and, *Proposed Site 13* (4.37 acres)—30590 Cochise Circle, Temecula (Riverside County). Additionally, the applicant is requesting to reduce the acreage of existing Site 6 and existing Site 10. Because the ASF only pertains to establishing or reorganizing a general-purpose zone, the application would have no impact on FTZ 153's authorized subzones.

In accordance with the Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is March 8, 2011. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to March 23, 2011.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's Web site, which is accessible via *http://www.trade.gov/ftz.* For further information, contact Christopher Kemp

at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: January 3, 2011.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–138 Filed 1–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 2–2011]

Foreign-Trade Zone 152—Burns Harbor, IN, Application for Reorganization (Expansion of Service Area) Under the Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Ports of Indiana, grantee of FTZ 152, requesting authority to reorganize its zone to expand its service area under the alternative site framework (ASF) adopted by the Board (74 FR 1170, 1/12/09 (correction 74 FR 3987, 1/22/09); 75 FR 71069–71070, 11/22/10). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 3, 2011.

FTZ 152 was approved by the Board on December 9, 1988 (Board Order 393, 53 FR 52454, 12/28/88) and expanded on March 9, 1992 (Board Order 563, 57 FR 9103, 3/16/92) and September 16, 1993 (Board Order 654, 58 FR 50330, 9/27/93). FTZ 152 was reorganized under the ASF on November 15, 2010 (Board Order 1723, 75 FR 72801, 11/26/2010).

The zone project currently has a service area that includes Lake, Porter, La Porte, Newton, Jasper and Starke Counties, Indiana. The applicant is requesting authority to expand the service area of the zone to include Pulaski and Fulton Counties, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The proposed expanded service area is adjacent to the Chicago Customs and Border Protection port of entry.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is March 8, 2011. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to March 23, 2011.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's website, which is accessible via *http://www.trade.gov/ftz.* For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: January 3, 2011.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–137 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 3–2011]

Foreign-Trade Zone 177—Evansville, IN; Application for Reorganization (Expansion of Service Area) Under the Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Ports of Indiana, grantee of FTZ 177, requesting authority to reorganize its zone to expand its service area under the alternative site framework (ASF) adopted by the Board (74 FR 1170, 1/12/09 (correction 74 FR 3987, 1/22/09); 75 FR 71069–71070, 11/22/10). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new "usage-driven" FTZ sites for operators/users located within a grantee's "service area" in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on January 3, 2011.

FTZ 177 was approved by the Board on March 12, 1991 (Board Order 513, 56 FR 12155, March 22, 1991) and expanded on July 2, 1993 (Board Order 648, 58 FR 37908, July 14, 1993). FTZ 177 was reorganized under the ASF on October 29, 2010 (Board Order 1721, 75 FR 68605, November 8, 2010).

The zone project currently has a service area that includes Vanderburgh, Dubois, Pike, Gibson, Knox, Daviess, Spencer, Warrick and Posey Counties, Indiana. The applicant is requesting authority to expand the service area of the zone to include Sullivan, Perry, Crawford, Orange and Martin Counties, as described in the application. If approved, the grantee would be able to serve sites throughout the expanded service area based on companies' needs for FTZ designation. The proposed expanded service area is adjacent to the Owensboro-Evansville Customs and Border Protection port of entry.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is March 8, 2011. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to March 23, 2011.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue, NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's Web site, which is accessible via *http://www.trade.gov/ftz.* For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: January 3, 2011.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–136 Filed 1–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1733]

Grant of Authority; Establishment of a Foreign-Trade Zone; Western Maricopa County, AZ

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''* * * the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection (CBP) ports of entry;

Whereas, Greater Maricopa Foreign Trade Zone, Inc. (the Grantee) has made application to the Board (FTZ Docket 60–2009, filed 12/18/09), requesting the establishment of a foreign-trade zone in Western Maricopa County; Arizona, adjacent to the Phoenix U.S. Customs and Border Protection port of entry;

Whereas, notice inviting public comment has been given in the **Federal Register** (74 FR 68785–68786, 12/29/09), and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiner's report, and finds that the requirements of the FTZ Act and Board's regulations are satisfied, and that approval of the application is in the public interest;

Now, therefore, the Board hereby grants to the Grantee the privilege of establishing a foreign-trade zone, designated on the records of the Board as Foreign-Trade Zone No. 277, at the sites described in the application, and subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 22nd day of December 2010.

Foreign-Trade Zones Board.

Gary Locke,

Secretary of Commerce, Chairman and Executive Officer.

Attest:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–135 Filed 1–6–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

Foreign-Trade Zone 147—Berks County, PA; Site Renumbering Notice

Foreign-Trade Zone 147 was approved by the Foreign-Trade Zones Board on June 28, 1988 (Board Order 378), and expanded on February 25, 1997 (Board Order 871), on November 3, 2005 (Board Order 1417), and on May 29, 2009 (Board Order 1615).

FTZ 147 currently consists of 15 ''sites'' totaling 3,007 acres in the Reading area. The current update does not alter the physical boundaries that have previously been approved, but instead involves an administrative renumbering that separates certain non-contiguous sites for record-keeping purposes.

Under this revision, the site list for FTZ 147 will be as follows: Site 1 (865 acres)—Reading Municipal Airport complex; Site 2 (7 acres)—Second Street and Grand Street, Hamburg; Site 3 (161 acres)—Excelsior Industrial Park, Maiden Creek Township; Site 4 (279 acres)—within the International Trade District of York; Site 5 (42 acres)—Penn Township Industrial Park; Site 6 (27 acres)—Hanover Terminal, Center Street at CSX Railroad, Hanover; Site 7 (155 acres)—Greenspring Industrial Park, 305 Green Springs Road, York County; Site 8 (153 acres)—Fairview Business Park, Lewisberry; Site 9 (185 acres)—Chambersburg Industrial Park; Site 10 (1214)—Cumberland Valley Business Park, Franklin County; Site 11 (310 acres)—ProLogis Park 81, Interstate 81 and Walnut Bottom Road, Cumberland County; Site 12 (242 acres)—LogistiCenter, Allen Road Extension and Distribution Drive, Carlisle; Site 13 (100 acres)—Capital Business Center, Dauphin County; Site 14 (164 acres)—Conewago Industrial Park, 1100 Zeager Road, Elizabethtown; Site 15 (214 acres)—600 & 601 Memory Lane, York; Site 16 (9 acres)—789 Kings Mill Road, York; and Site 17 (24 acres)—401 Moulstown Road, Penn Township.

FOR FURTHER INFORMATION CONTACT: Maureen Hinman at *maureen.hinman@trade.gov* or (202) 482–0627.

Pierre V. Duy,

Acting Executive Secretary.

[FR Doc. 2011–139 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–918]

Steel Wire Garment Hangers From the People's Republic of China: Extension of Time Limit for Final Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce

DATES: *Effective Date:* January 7, 2011.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik or Josh Startup, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–6905 or (202) 482–5260 respectively.

Background

On November 9, 2010, the Department of Commerce (''Department'') published the preliminary results of this administrative review. *See Steel Wire Garment Hangers From the People's Republic of China: Preliminary Results and Preliminary Rescission, in Part, of the First Antidumping Duty Administrative Review,* 75 FR 68758 (November 9, 2010) (''*Preliminary Results*''). The final results are currently due on March 9, 2011.

Extension of Time Limits for Final Results

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (''Act''), requires the Department to issue the final results in an administrative review of an antidumping duty order 120 days after the date on which the preliminary results are published. The Department may, however, extend the deadline for completion of the final results of an administrative review by an additional 60 days if it determines it is not practicable to complete the review within the foregoing time period. *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

As we stated in the *Preliminary Results,* the Department requires additional information from certain respondents in this review, thus no deadline was established therein for the submission of case briefs and rebuttal briefs. Following the *Preliminary Results,* the Department also issued a supplemental questionnaire to one of the respondents in this review. Because the Department requires additional time to review the respondent's supplemental questionnaire response,

review interested parties' case and rebuttal briefs after setting a submission deadline, and conduct the public hearing that was requested by interested parties, we have determined that it is not practicable to complete this review within the 120 days specified under the Act. Therefore, we are extending the time for the completion of the final results of this review by 60 days to May 8, 2011.[1]

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: January 3, 2011.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–143 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–933]

Frontseating Service Valves From the People's Republic of China: Extension of Time for the Preliminary Results of the Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* January 7, 2011.

FOR FURTHER INFORMATION CONTACT: Laurel LaCivita, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–4243.

SUPPLEMENTARY INFORMATION:

Background

On May 28, 2010, the Department of Commerce ("the Department") published in the **Federal Register** a notice of initiation of an administrative review of the antidumping duty order on frontseating service valves for Zhejiang Sanhua Co., Ltd. and Zhejiang DunAn Hetian Metal Co., Ltd. for the period October 22, 2008, through March 31, 2010.[1] Currently, the preliminary results of review are due no later than December 31, 2010. Because December 31, 2010, falls on a Federal holiday, a non-business day, the deadline for the preliminary results reverts to January 3, 2011, the next business day following the Federal holiday.[2]

Extension of Time Limit of Preliminary Results

Pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended ("the Act"), the Department shall make a preliminary determination in an administrative review of an antidumping duty order within 245 days after the last day of the anniversary month of the date of publication of the order. The Act further provides, however, that the Department may extend that 245-day period to 365 days if it determines it is not practicable to complete the review within the foregoing time period.

We determine that completion of the preliminary results of this review within the 245-day period is not practicable because the Department requires additional time to analyze information pertaining to the respondent's sales practices, factors of production, and to issue and review responses to supplemental questionnaires. Therefore, we require additional time to complete these preliminary results. As a result, in accordance with section 751(a)(3)(A) of the Act, the Department is extending the time period for completion of the preliminary results of this review by 120 days until April 30, 2011. However, April 30, 2011, falls on a weekend, and it is the Department's long-standing practice to issue a determination on the next business day when the statutory deadline falls on a weekend.[3] Accordingly, the deadline for completion of the preliminary results of the review is now no later than May 2, 2011.

This notice is published in accordance with sections 751(a)(3)(A) and 777(i) of the Act.

Dated: December 30, 2010.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2011–62 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–DS–P

[1] Department practice dictates that where a deadline falls on a weekend, the appropriate deadline is the next business day. *See Notice of Clarification: Application of* "*Next Business Day*" *Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005). Therefore, the final results of this review will be due on May 9, 2011.

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 75 FR 29976 (May 28, 2010).

[2] *See Notice of Clarification: Application of* "*Next Business Day*" *Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533 (May 10, 2005) ("*Next Business Day Rule*").

[3] *See Next Business Day Rule.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–807]

Polyethylene Terephthalate Film, Sheet, and Strip From the Republic of Korea: Final Results of the Expedited Third Five-Year (Sunset) Review of the Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On September 1, 2010, the Department of Commerce (the Department) initiated the third sunset review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip from the Republic of Korea, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). The Department has conducted an expedited (120-day) sunset review pursuant to 19 CFR 351.218(e)(1)(ii)(C)(2). As a result of this sunset review, the Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping at the levels indicated in the "Final Results of Review" section of this notice.

FOR FURTHER INFORMATION CONTACT: Contact Tyler Weinhold or Robert James, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1121, or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION

Background

On September 1, 2010, the Department initiated the third sunset review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip from the Republic of Korea, pursuant to section 751(c) of the Act. *See Initiation of Five-Year ("Sunset") Review,* 75 FR 53664 (September 1, 2010) (*Notice of Initiation*).

The Department received a notice of intent to participate from DuPont Teijin Films, Mitsubishi Polyester Film, Inc., SKC, Inc., and Toray Plastics (America), Inc. (collectively, "petitioners" or "domestic interested parties"), within the deadline specified in 19 CFR 351.218(d)(1)(i). The petitioners claimed domestic interested party status under section 771(9)(C) of the Act stating that they are producers in the United States of a domestic like product.

The Department received a response to the *Notice of Initiation* from the

domestic interested parties on October 1, 2010, within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). On October 20, 2010, the domestic interested parties submitted a correction to their response, correcting certain inaccuracies. We received no substantive responses from respondent interested parties. We determined the response of the domestic interested parties to be an adequate substantive response in accordance with 19 CFR 351.218(d)(3). As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited (120-day) sunset review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip from the Republic of Korea.

Scope of the Order

Imports covered by the order are shipments of all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet, and strip, whether extruded or coextruded. The films excluded from this review are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer more than 0.00001 inches (0.254 micrometers) thick.

Polyethylene terephthalate film, sheet, and strip is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 3920.62.00. The HTSUS subheading is provided for convenience and for customs purposes. The written description remains dispositive as to the scope of the product coverage.

Analysis of Comments Received

All issues raised in this sunset review are addressed in "Issues and Decision Memorandum for the Final Results of Expedited Third Sunset Review of the Antidumping Duty Order on Polyethylene Terephthalate Film, Sheet, and Strip from the Republic of Korea" from Edward C. Yang, Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Deputy Assistant Secretary for Import Administration (Issues and Decision Memorandum), which is hereby adopted by, and issued concurrently with, this notice. The issues discussed in the Issues and Decision Memorandum are the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the order was revoked. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum which is on file in the Central Records Unit, room 7046 of the main Commerce Department building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Web at *http://ia.ita.doc.gov/frn.* The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Review

We determine that revocation of the antidumping duty order on polyethylene terephthalate film, sheet and strip from the Republic of Korea would be likely to lead to continuation or recurrence of dumping at the following weighted-average percentage margins:

Manufacturers/Exporters/ Producers	Weighted-average margin (percent)
SKC Limited	13.92
All Others	21.50

These dumping margins are from the Less-Than-Fair-Value Investigation, as amended pursuant to remand in *E.I. Dupont de Nemours & Co., Inc.* v. *United States,* 954 F. Supp. 263 (CIT 1997). *See Polyethylene Terephthalate Film, Sheet, and Strip From the Republic of Korea; Notice of Final Court Decision and Amended Final Determination of Antidumping Duty Investigation,* 62 FR 50557 (September 26, 1997).

Notification to Interested Parties

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: December 29, 2010.

Edward C. Yang,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 2011–145 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Electroshock Weapons Test and Measurement Workshop

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: NIST invites stakeholders (manufacturers, law enforcement, corrections, academia, military, test instrument manufacturers, *etc.*) of electroshock weapons that provide stand-off delivery of an electric shock to attend a public meeting. The purpose of the meeting is to discuss the need for standardized methods of testing the proper operation and performance of ESWs as well as other issues important to the stakeholder community. Attendance is limited to 45 and registration will be conducted on a first-come first-served basis. Teleconferencing will also be available and also requires pre-registration.

DATES: The public meeting will be held on Friday, 21 January 2011 from 0900 to 1700.

ADDRESSES: The public meeting will be held at NIST, 100 Bureau Drive, Gaithersburg, MD. Information on accommodations, location, and travel can be found at: *http://www.nist.gov/public_affairs/visitor/visitor.htm.* Please note admittance and teleconference participation instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Cindy Stanley at 301–975–2756 or by e-mail at *cindy.stanley@nist.gov.*

SUPPLEMENTARY INFORMATION: To support the development of rigorous performance requirements for electroshock weapons, the Law Enforcement Standards Office (OLES) at NIST has developed methods to measure the current and high-voltage output of these weapons, to calibrate these measurement methods, and to compute measurement uncertainties.

All visitors to the NIST site are required to pre-register to be admitted. Anyone wishing to attend this meeting must register by close of business Friday, 14 January 2011. Please contact Cindy Stanley with your interest to participate and, pending availability of space, she will provide you with instructions for admittance. Non-U.S. citizens must also complete form NIST 1260, which can be requested from Cindy Stanley. Cindy Stanley's e-mail

address is *cindy.stanley@nist.gov* and phone number is 301–975–2756.

In addition, members of the public who wish to participate in the meeting by teleconference must provide Ms. Stanley with their name, email address, and telephone number. Ms. Stanley will provide teleconference information prior to the meeting.

Dated: January 4, 2011.

Charles H. Romine,

Acting Associate Director for Laboratory Programs.

[FR Doc. 2011–114 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–13–P

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Amendment of Limitation of Duty- and Quota-Free Imports of Apparel Articles Assembled in Beneficiary ATPDEA Countries From Regional Country Fabric

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Amending the 12-Month Cap on Duty and Quota Free Benefits.

DATES: *Effective Date:* January 1, 2011.

FOR FURTHER INFORMATION CONTACT: Richard Stetson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–3400.

SUPPLEMENTARY INFORMATION:

Authority: Section 3103 of the Trade Act of 2002, Pub. L. 107–210; Presidential Proclamation 7616 of October 31, 2002, 67 FR 67283 (November 5, 2002); Executive Order 13277, 67 FR 70305 (November 19, 2002); and the Office of the United States Trade Representative's Notice of Authority and Further Assignment of Functions, 67 FR 71606 (November 25, 2002).

Section 3103 of the Trade Act of 2002 amended the Andean Trade Preference Act (ATPA) to provide for duty and quota-free treatment for certain textile and apparel articles imported from designated Andean Trade Promotion and Drug Eradication Act (ATPDEA) beneficiary countries. Section 204(b)(3)(B)(iii) of the amended ATPA provides duty- and quota-free treatment for certain apparel articles assembled in ATPDEA beneficiary countries from regional fabric and components, subject to quantitative limitation. More specifically, this provision applies to apparel articles sewn or otherwise assembled in one or more ATPDEA beneficiary countries from fabrics or from fabric components formed or from components knit-to-shape, in one or more ATPDEA beneficiary countries, from yarns wholly formed in the United States or one or more ATPDEA beneficiary countries (including fabrics not formed from yarns, if such fabrics are classifiable under heading 5602 and 5603 of the Harmonized Tariff Schedule (HTS) and are formed in one or more ATPDEA beneficiary countries). Such apparel articles may also contain certain other eligible fabrics, fabric components, or components knit-to-shape.

Title VII of the Tax Relief and Health Care Act (TRHCA) of 2006, Pub L. No. 107–432, extended the expiration of the ATPA to June 30, 2007. *See* Section 7002(a) of the TRHCA 2006. H.R. 1830, 110th Cong. (2007), further extended the expiration of the ATPA to February 29, 2008. H.R. 5264, 110th Cong. (2008), further extended the expiration of the ATPA to December 31, 2008. H.R. 7222, 110th Cong. (2008), further extended the expiration of the ATPA to December 31, 2009. H.R 4284, 111th Cong. (2009), further extended the expiration of the ATPA to December 31, 2010. H.R 6517, 111th Cong. (2010), further extended the expiration of the ATPA to February 12, 2011.

The purpose of this notice is to extend the period of the quantitative limitation for preferential tariff treatment under the regional fabric provision for imports of qualifying apparel articles from Colombia and Ecuador for a six-week period, through February 12, 2011. With respect to qualifying apparel articles from Peru, the termination of preferential treatment is effective December 31, 2010.

For the period beginning on October 1, 2010 and extending through February 12, 2011, the aggregate quantity of imports eligible for preferential treatment under the regional fabric provision is 1,238,203,339 square meters equivalent. Apparel articles entered in excess of this quantity will be subject to otherwise applicable tariffs.

This quantity is calculated using the aggregate square meter equivalents of all apparel articles imported into the United States, derived from the set of Harmonized System lines listed in the Annex to the World Trade Organization Agreement on Textiles and Clothing (ATC), and the conversion factors for units of measure into square meter equivalents used by the United States in implementing the ATC.

Janet E. Heinzen,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 2011–141 Filed 1–6–11; 8:45 am]

BILLING CODE 3510–DS–P

CONSUMER PRODUCT SAFETY COMMISSION

Publicly Available Consumer Product Safety Information Database: Notice of Public Web Conferences

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission ("Commission," "CPSC," or "we") is announcing two Web conferences to demonstrate to interested stakeholders the incident reporting form, industry registration and comment features, and the search function of the publicly available consumer product safety information database ("Database"). The Web conferences will be webcast live from the Commission's headquarters in Bethesda, MD via the Internet on January 11, 2011, and January 20, 2011. Stakeholders may participate in person or online.

DATES: The first Web conference will be held from 10:30 a.m. to 12:30 p.m. on Tuesday, January 11, 2011, and the second Web conference will be held from 10:30 a.m. to 12:30 p.m. on Thursday, January 20, 2011.

ADDRESSES: The Web conferences will be webcast from the CPSC's headquarters at the Bethesda Towers Building, 4330 East West Highway, Bethesda, MD 20814. Persons interested in attending either Web conference in person should register in advance online at *http://www.cpsc.gov/meetingsignup.html.* Persons interested in participating online via the webcast should register in advance for the January 11th Web conference online at *http://www3.gotomeeting.com/register/757140102,* and for the January 20th Web conference online at *http://www3.gotomeeting.com/register/396775014.* Registration for in person or online attendance of either Web conference can also be completed by sending an electronic mail (e-mail), calling, or writing to Todd A. Stevenson, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; e-mail *cpsc-os@cpsc.gov;* telephone (301) 504–7923; facsimile (301) 504–0127. The CPSC Web link also has more information about each Web conference.

FOR FURTHER INFORMATION CONTACT: Ming Zhu, Office of Information & Technology Services, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; *mzhu@cpsc.gov;* telephone (301) 504–7517.

SUPPLEMENTARY INFORMATION: Section 212 of the Consumer Product Safety Improvement Act of 2008 (Pub. L. 110–314) ("CPSIA") requires the Commission to establish and maintain a product safety information database that is available to the public. Specifically, section 212 of the CPSIA amended the Consumer Product Safety Act ("CPSA") to create a new section 6A of the CPSA, titled "Publicly Available Consumer Product Safety Information Database" ("Database"). Section 6A(a)(1) of the CPSA requires the Commission to establish and maintain a database on the safety of consumer products, and other products or substances regulated by the Commission. The Database must be publicly available, searchable, and accessible through the Commission's Web site.

In the **Federal Register** of December 9, 2010 (75 FR 76832), we published a final rule to establish the Database. The final rule will become effective on January 10, 2011.

Through this notice, we are announcing that we will conduct two Web conferences to demonstrate certain aspects of the Database. The first Web conference, which will be held on January 11, 2011, will focus on the incident form that the public will use to file a report of harm and the search function of the Database. The Web conference is intended to inform all interested stakeholders of the information required on the form to be used to report an incident, in addition to an explanation of the public search function of the Database.

The second Web conference, which will be held on January 20, 2011, will focus on the industry registration and comment features, the process for reporting incidents, and the public search component of the Database.

Persons interested in viewing either Web conference or attending a webcast in person should register in advance as explained in the **ADDRESSES** section of this notice. The CPSC Web link at *http://www.cpsc.gov/meetingsignup.html* has more information about the demonstrations.

Dated: January 3, 2011.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2011–120 Filed 1–6–11; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2010–OESE–0018]

Enhanced Assessment Instruments

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of proposed priorities, requirements, definitions, and selection criteria.

SUMMARY: The Secretary of Education proposes priorities, requirements, definitions, and selection criteria under the Enhanced Assessment Instruments Grant (EAG) competition. The Secretary may use one or more of these priorities, requirements, definitions, and selection criteria for competitions using funds from fiscal year (FY) 2010 and later years. We take these actions in order to establish selection criteria that are likely to recognize high-quality proposals and to help focus Federal financial assistance on applications that address pressing needs and promising developments related to developing and implementing assessments under the Elementary and Secondary Education Act of 1965, as amended (ESEA).

DATES: We must receive your comments on or before February 7, 2011. We encourage you to submit comments well in advance of this date.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by e-mail. Please submit your comments only one time in order to ensure that we do not receive duplicate copies. In addition, please include the Docket ID and the term "Enhanced Assessment Grants—Comments" at the top of your comments.

Federal eRulemaking Portal: Go to *http://www.regulations.gov* to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under "How To Use This Site." A direct link to the docket page is also available at *http://www.ed.gov/programs/eag.*

Postal Mail, Commercial Delivery, or Hand Delivery. If you mail or deliver your comments about these proposed priorities, requirements, definitions, and selection criteria, address them to the Office of Elementary and Secondary Education (Attention: Enhanced Assessment Grants Comments), U.S. Department of Education, 400 Maryland Avenue, SW., room 3W210, Washington, DC 20202.

Privacy Note: The Department's policy for comments received from members of the public (including those comments submitted by mail, commercial delivery, or hand delivery) is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at *http://www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available on the Internet.

FOR FURTHER INFORMATION CONTACT: Collette Roney. Telephone: (202) 401–5245 or by e-mail: *collette.roney@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: *Invitation to Comment:* We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priorities, requirements, definitions, and selection criteria, we urge you to identify clearly the specific proposed priority, requirement, definition, or selection criterion that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed priorities, requirements, definitions, and selection criteria. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice by accessing Regulations.gov. You may also inspect the comments in person, in room 3W210, 400 Maryland Avenue, SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the Enhanced Assessment Instruments Grant (EAG) program is to enhance the

quality of assessment instruments and systems used by States for measuring the academic achievement and growth of elementary and secondary students.

Program Authority: 20 U.S.C. 7301a.

Proposed Priorities:

Background:

Proficiency on the State assessments required under Title I, Part A of the ESEA is the primary indicator of student academic achievement and, hence, a crucial measure of State success in meeting the goals of the ESEA. In view of the critical importance of these State assessments, section 6112 of the ESEA authorizes the Department, through the EAG program, to make competitive grant awards to State educational agencies (SEAs) to help them enhance the quality of their assessment instruments and assessment systems. The EAG program includes four statutory priorities:

(a) Collaborating with institutions of higher education, other research institutions, or other organizations to improve the quality, validity, and reliability of State academic assessments beyond the requirements for these assessments described in section 1111(b)(3) of the ESEA;

(b) Measuring student academic achievement using multiple measures of student academic achievement from multiple sources;

(c) Charting student progress over time; and

(d) Evaluating student academic achievement through the development of comprehensive academic assessment instruments, such as performance- and technology-based academic assessments.

EAG grantees must address one or more of these statutory priorities. Through this notice, the Department proposes two additional priorities as well as requirements, definitions, and selection criteria that are designed to support States' assessment work and to build upon the assessments that the Department is funding through the Race to the Top Assessment (RTTA) program.

Under the RTTA program, the Department awarded grants to two consortia, which collectively include 44 States and the District of Columbia, to support the development of new assessment systems that will be used by multiple States; are valid, reliable, and fair for their intended purposes and for all student subgroups; and measure student knowledge and skills against a common set of college- and career-ready standards in English language arts and mathematics.

The Department is also funding work on assessment development through the General Supervision Enhancement Grants (GSEG) program, which is authorized by the Individuals with Disabilities Education Act. The Department recently awarded funds under the GSEG program to support two consortia of States in developing alternate assessments based on alternate academic achievement standards for students with the most significant cognitive disabilities that fit coherently with assessments being developed under the RTTA program.

Section 1111(b)(7) of the ESEA requires States receiving ESEA Title I, Part A allocations to administer, on a yearly basis, valid and reliable assessments of the English language proficiency of all English learners and, under section 3122 of the ESEA, States receiving funds under Title III, Part A, Subpart 1 of the ESEA must use the results of these English language proficiency assessments for accountability purposes. The English language proficiency assessments developed to date have been designed to align with English language proficiency standards that correspond with State-specific standards in reading/language arts and mathematics. States need English language proficiency assessments, however, that align with English language proficiency standards that correspond to standards that prepare students for college and the workplace. The Department did not include English language proficiency assessments among the priorities established in the notice inviting applications for the RTTA program. Accordingly, we propose here a priority for the EAG program for projects that propose to develop a system of English language proficiency assessments aligned with English language proficiency standards that correspond to a common set of college- and career-ready standards (as defined in the definitions section in this notice) in English language arts and mathematics that will be operational by the end of the project period (i.e., ready for large-scale administration). These assessments would complement the assessments that are being developed under the RTTA program.

This priority would support the development of an English language proficiency assessment system for English learners, as specified in the priority. This priority would not support the development of English language proficiency assessments for English learners with the most significant cognitive disabilities who are eligible to participate in alternate assessments based on alternate academic achievement standards in accordance with 34 CFR 200.6(a)(2). The Department previously awarded a grant to support the development of alternate assessments of English language proficiency for such English learners through a prior EAG competition. In addition, through the GSEG program, the Department is currently funding the development of alternate assessments based on alternate academic achievement standards that measure student knowledge and skills against a set of college- and career-ready standards in English language arts and mathematics held in common by multiple States. We believe that these investments in alternate assessments will help prepare the field for developing the next generation of English language proficiency assessments for English learners with the most significant cognitive disabilities.

The Department notes that, while this priority would not support the development of English language proficiency assessments for English learners with the most significant cognitive disabilities, all States remain responsible, in accordance with section 1111(b)(7) of the ESEA, for assessing the English language proficiency of all English learners, including English learners with the most significant cognitive disabilities. We are therefore including in the priority a requirement that an applicant describe the strategies it and, if it applies as part of a consortium, all States in the consortium would use to assess the English language proficiency of English learners with the most significant cognitive disabilities in lieu of including them in the operational administration of the assessments developed for other English learners under a grant from this competition.

The Department plans to fund grant awards for at least a three-year project period to develop operational assessments for an English language proficiency assessment system.

During public meetings the Department held to gain input on the design of the RTTA program's fiscal year (FY) 2010 competition, and in other arenas, States indicated to the Department their interest in continuing to work together in consortia to develop assessments aligned with common State-developed standards. Therefore, we propose a priority for the EAG program that would support projects that propose collaborative efforts among States.

The Secretary may apply one or more of these priorities in any year in which the program is in effect.

Proposed Priority 1—English Language Proficiency Assessment System.

Background:

English learners (as defined in this notice) must acquire both English language proficiency and content area knowledge in order to succeed in school and graduate from high school college- and career-ready. In order to inform teaching, learning, and program improvement, educators need data from assessments about the English language proficiency level of each English learner and his or her progress toward attainment of proficiency in English. Assessments that provide that information would also assist in building the knowledge base about promising practices to improve English proficiency and thus support efforts to improve instruction for English learners.

Proposed Priority 1 would support the development of high-quality English language proficiency assessments that are aligned with English language proficiency standards that in turn correspond to a common set of college- and career-ready standards in English language arts and mathematics. States in a consortium developing these English language proficiency assessments would use a common definition of "English learner" and common criteria for exiting a student from English learner status in order to ensure consistent identification of students as English learners across member States. These assessments also would be used to help determine the effectiveness of English language instruction educational programs.

Proposed Priority 1:

To meet this priority, an applicant must propose a comprehensive plan to develop an English language proficiency assessment system that is valid, reliable, and fair for its intended purpose. Such a plan must include the following features:

(a) *Design.* The assessment system must—

(1) Be designed for implementation in multiple States;

(2) Be based on a common definition of "English learner" adopted by the applicant State and, if the applicant applies as part of a consortium, adopted and held in common by all States in the consortium;

(2) At a minimum, include diagnostic (placement) and summative assessments;

(3) Measure students' English language proficiency against a set of English language proficiency standards held by the applicant State and, if the applicant applies as part of a consortium, held in common by all States in the consortium, that correspond to a common set of college- and career-ready standards (as defined in this notice) in English language arts and mathematics;

(4) Cover the full range of the English language proficiency standards across the four language domains of reading, writing, speaking, and listening, as required by section 3113(b)(2) of the ESEA;

(5) Measure the linguistic components of language (e.g., phonology, morphology, syntax, vocabulary);

(6) Produce results that indicate whether individual students have attained the English language proficiency necessary to participate fully in academic instruction in English and meet or exceed college- and career-ready standards;

(7) Provide at least an annual measure of English language proficiency and student progress in learning English for English learners in grades kindergarten through 12 in each of the four language domains;

(8) Assess all English learners, including English learners who are also students with disabilities and students with limited or no formal education, except for English learners with the most significant cognitive disabilities who are eligible to participate in alternate assessments based on alternate academic achievement standards; and

(9) Be accessible to all English learners, including by providing appropriate accommodations for English learners with disabilities, except for English learners with the most significant cognitive disabilities who are eligible to participate in alternate assessments based on alternate academic achievement standards.

(b) *Technical Quality.* The assessment system must measure students' English language proficiency in ways that—

(1) Are consistent with nationally recognized professional and technical standards; and

(2) As appropriate, elicit complex student demonstrations of comprehension and production of academic English (e.g., performance tasks, selected responses, brief or extended constructed responses).

(c) *Data.* The assessment system must produce data, that—

(1) Include student attainment of English language proficiency and student progress in learning English,

(2) Indicate students' abilities in each of the four language domains and provide a comprehensive English language proficiency score based on all four domains, for students at each proficiency level; and

(3) Can be used to inform—

(i) Identification of students as English learners;

(ii) Decisions about whether a student should exit from English language instruction educational programs;

(iii) Determinations of school, local educational agency (LEA), and State effectiveness for the purposes of accountability under Title I and Title III of the ESEA;

(iv) Determinations of individual principal and teacher effectiveness for purposes of evaluation;

(v) Determinations of principal and teacher professional development and support needs; and

(vi) Improvement in teaching, learning, and language instruction education programs.

(d) *Compatibility.* The assessment system must use compatible approaches to technology, assessment administration, scoring, reporting, and other factors that facilitate the coherent inclusion of the assessments within States' student assessment systems.

(e) *Students with the most significant cognitive disabilities.* The comprehensive plan to develop an English language proficiency assessment system must include the strategies the applicant State and, if the applicant is part of a consortium, all States in the consortium plan to use to assess the English language proficiency of English learners with the most significant cognitive disabilities who are eligible to participate in alternate assessments based on alternate academic achievement standards in accordance with 34 CFR 200.6(a)(2) in lieu of including those students in the operational administration of the assessments developed for other English learners under a grant from this competition.

Proposed Priority 2—Collaborative Efforts Among States.

Background:

Two consortia of States are collaborating under the RTTA program to develop new assessment systems that measure student knowledge and skills against a common set of college- and career-ready standards in English language arts and mathematics. States also have indicated to the Department their interest in continuing to work together in consortia to develop assessments aligned to common standards. Because of the complexity of developing and implementing assessments and other assessment-related instruments, collaborative efforts between and among States can yield approaches that build on each State's expertise and experience as well as approaches that generate efficiencies in development, administration, costs, and

uses of results. In previous competitions for EAG funds, which also included a priority for collaboration among States, States often responded by proposing consortia to complete a range of projects. In light of the interest among States, the benefits of collaboration, and the prior practice within the EAG program, the Department also proposes a priority for projects that involve collaborative efforts among States.

Proposed Priority:

To meet this priority, an applicant must—

(a) Include a minimum of 15 States in the consortium;

(b) Identify in its application a proposed project management partner and provide an assurance that the proposed project management partner is not partnered with any other eligible applicant applying for an award under this competition;

(c) Provide a description of the consortium's structure and operation. The description must include—

(1) The organizational structure of the consortium (e.g., differentiated roles that a member State may hold);

(2) The consortium's method and process (e.g., consensus, majority) for making different types of decisions (e.g., policy, operational);

(3) The protocols by which the consortium will operate, including the protocols for member States to change roles in the consortium;

(4) The consortium's plan, including the process and timeline, for setting key policies and definitions for implementing the proposed project, including, for any assessments developed through a project funded by this grant, the common set of standards upon which to base the assessments, a common set of performance-level descriptors, a common set of achievement standards, common assessment administration procedures, common item-release and test-security policies, and a common set of policies and procedures for accommodations and student participation; and

(5) The consortium's plan for managing grant funds received under this competition; and

(d) Provide a memorandum of understanding or other binding agreement executed by each State in the consortium that includes an assurance that the State will adopt or utilize any instrument, including to the extent applicable, any standards or assessments, developed under the proposed project no later than the end of the project period.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

PROPOSED REQUIREMENTS:

Background:

Like the priorities and selection criteria that we are proposing in this notice for the EAG program, the proposed program requirements for this program are closely aligned with those that we established for the RTTA program. These proposed requirements have been designed to ensure that any assessments or other assessment-related instruments developed under a grant for this program are operational by the end of the grant period, meet high standards of technical quality, and use the benefits of technology as well as enable wide-spread availability and usability of the assessments or other assessment-related instruments developed.

Proposed Requirements:

The Secretary proposes the following requirements for this program. We may apply one or more of these requirements in any year in which this program is in effect. An eligible applicant awarded a grant under this program must—

(a) Evaluate the validity, reliability, and fairness of any assessments or other assessment-related instruments developed under a grant from this competition, and make available documentation of evaluations of technical quality through formal mechanisms (e.g., peer-reviewed journals) and informal mechanisms (e.g., newsletters), both in print and electronically;

(b) Actively participate in any applicable technical assistance activities conducted or facilitated by the Department or its designees (e.g., the RTTA program), and participate in other activities as determined by the Department;

(c) Develop a strategy to make student-level data that result from any assessments or other assessment-related instruments developed under a grant from this competition available on an ongoing basis for research, including for prospective linking, validity, and program improvement studies;

(d) Ensure that any assessments or other assessment-related instruments developed under a grant from this competition will be operational at the end of the project period (e.g., ready for large-scale administration);

(e) Maximize the interoperability of any assessments and other assessment-related instruments developed with funds from this competition across technology platforms and the ability for States to move their assessments from one technology platform to another by doing the following, as applicable, for any assessments developed with funds from this competition—

(1) Developing all assessment items in accordance with an industry-recognized open-licensed interoperability standard that is approved by the Department during the grant period, without non-standard extensions or additions; and

(2) Producing all student-level data in a manner consistent with an industry-recognized open-licensed interoperability standard that is approved by the Department during the grant period;

(f) Unless otherwise protected by law or agreement as proprietary information, making any assessment content (i.e., assessments and assessment items) and other assessment-related instruments developed with funds from this competition freely available to States, technology platform providers, and others that request it for purposes of administering assessments, provided that those requesting assessment content comply with consortium or State requirements for test or item security; and

(g) For any assessments and other assessment-related instruments developed with funds from this competition, using technology to the maximum extent appropriate to develop, administer, and score the assessments and report results.

Proposed Definitions:

Background:

Several important terms associated with the EAG program's proposed priorities and selection criteria are not defined in the EAG statute.

Proposed Definitions

The Secretary proposes the following definitions for the EAG program. We may apply one or more of these

definitions in any year in which this program is in effect.

Common set of college- and career-ready standards means a set of academic content standards for grades K–12 held in common by a significant number of States, that (a) define what a student must know and be able to do at each grade level; (b) if mastered, would ensure that the student is college- and career-ready by the time of high school graduation; and (c) for any consortium of States applying under the EAG program, are substantially identical across all States in the consortium.

A State in the consortium may supplement the common set of college- and career-ready standards with additional content standards, provided that the additional standards do not comprise more than 15 percent of the State's total standards for that content area.

English learner means a student who is an English learner as defined by the applicant consistent with the definition of a student who is "limited English proficient" as that term is defined in section 9101(25) of the ESEA. If the applicant submits an application on behalf of a consortium, member States must develop and adopt a uniform definition of the term during the period of the grant.

Student with a disability means a student who has been identified as a child with a disability under the Individuals with Disabilities Education Act, as amended.

Proposed Selection Criteria:

Background:

We expect that any assessments funded under this competition will be of similar technical quality to those funded under the RTTA program. Therefore, the proposed selection criteria are adapted from the selection criteria that the Department used to review applications under that program.

Proposed Selection Criteria:

The Secretary proposes the following selection criteria for evaluating an application under this program. We may apply one or more of these criteria in any year in which this program is in effect. In the notice inviting applications or the application package or both we will announce the selection criteria to be applied and the maximum possible points assigned to each criterion.

(a) *Theory of action.* The Secretary reviews each application to determine the extent to which the eligible applicant's theory of action is logical, coherent, and credible, and will result in improved student outcomes. In determining the extent to which the theory of action has these attributes, we will consider the description of, and rationale for—

(1) How the assessment results will be used (e.g., at the State, LEA, school, classroom, and student levels);

(2) How the assessments and assessment results will be incorporated into coherent educational systems of the State(s) participating in the grant (i.e., systems that include standards, assessments, curriculum, instruction, and professional development); and

(3) How those educational systems as a whole will improve student achievement.

(b) *Assessment design.* The Secretary reviews each application to determine the extent to which the design of the eligible applicant's proposed assessments is innovative, feasible, and consistent with the theory of action. In determining the extent to which the design has these attributes, we will consider—

(1) The number and types of assessments, as appropriate (e.g., diagnostic assessments, summative assessments);

(2) How the assessments will measure student knowledge and skills against the full range of the relevant standards, including the standards against which student achievement has traditionally been difficult to measure, provide an accurate measure of student proficiency on those standards, including for students who are high- and low-performing in academic areas, and provide an accurate measure of student progress in the relevant area over a full academic year;

(3) How the assessments will produce the required student performance data, as described in the priority;

(4) How and when during the academic year different types of student data will be available to inform and guide instruction, interventions, and professional development;

(5) The types of data that will be produced by the assessments, which must include student achievement data and other data specified in the relevant priority;

(6) The uses of the data that will be produced by the assessments, including (but not limited to)—

(i) Determining individual student achievement and student progress; determining individual principal and teacher effectiveness, if applicable, and professional development and support needs;

(ii) Informing teaching, learning, and program improvement; and

(7) The frequency and timing of administration of the assessments, and the rationale for these;

(8) The number and types of items (e.g., performance tasks, selected responses, observational rating, brief or extended constructed responses) and the distribution of item types within the assessments, including the extent to which the items will be varied and elicit complex student demonstrations or applications of knowledge, skills, and approaches to learning, as appropriate (descriptions should include a concrete example of each item type proposed); and the rationale for using these item types and their distributions;

(9) The assessments' administration mode (e.g., paper-and-pencil, teacher rating, computer-based, or other electronic device), and the rationale for the mode;

(10) The methods for scoring student performance on the assessments, the estimated turnaround times for scoring, and the rationale for these; and

(11) The reports that will be produced based on the assessments, and for each report, its intended use, target audience (e.g., students, parents, teachers, administrators, policymakers), and the key data it will present.

(c) *Assessment development plan.* The Secretary reviews each application to determine the extent to which the eligible applicant's plan for developing the proposed assessments will ensure that the assessments are ready by the end of the grant period for wide-scale administration in a manner that is timely, cost-effective, and consistent with the proposed design and incorporates a process for ongoing feedback and improvement. In determining the extent to which the assessment development plan has these attributes, we will consider—

(1)(i) The approaches for developing assessment items (e.g., evidence-centered design, universal design) and the rationale for using those approaches; and the development phases and processes to be implemented consistent with the approaches; and

(ii) The types of personnel involved in each development phase and process (e.g., practitioners, content experts, assessment experts, experts in assessing English learners, linguists, experts in second language acquisition, experts in assessing students with disabilities, psychometricians, cognitive scientists, institution of higher education representatives, experts on career readiness standards);

(2) The approach and strategy for designing and developing accommodations, accommodation policies, and methods for standardizing the use of those accommodations for students with disabilities;

(3) The approach and strategy for ensuring scalable, accurate, and consistent scoring of items, including the approach and moderation system for any human-scored items and the extent to which teachers are trained and involved in the administration and scoring of assessments;

(4) The approach and strategy for developing the reporting system; and

(5) The overall approach to quality control and the strategy for field-testing assessment items, accommodations, scoring systems, and reporting systems, including, with respect to assessment items and accommodations, the use of representative sampling of all types of student populations, taking into particular account high- and low-performing students and different types of English learners and students with disabilities.

(d) *Research and evaluation.* The Secretary reviews each application to determine the extent to which the eligible applicant's research and evaluation plan will ensure that the assessments developed are valid, reliable, and fair for their intended purposes. In determining the extent to which the research and evaluation plan has these attributes, we will consider—

(1) The plan for identifying and employing psychometric techniques suitable for verifying, as appropriate to each assessment, its construct, consequential, and predictive validity; external validity; reliability; fairness; precision across the full performance continuum; and comparability within and across grade levels; and

(2) The plan for determining whether the assessments are being implemented as designed and the theory of action is being realized, including whether the intended effects on individuals and institutions are being achieved.

(e) *Professional capacity and outreach.* The Secretary reviews each application to determine the extent to which the eligible applicant's plan for implementing the proposed assessments is feasible, cost-effective, and consistent with the theory of action. In determining the extent to which the implementation plan has these attributes, we will consider—

(1) The plan for supporting teachers and administrators in implementing the assessments and for developing, in an ongoing manner, their professional capacity to use the assessments and results to inform and improve instructional practice; and

(2) The strategy and plan for informing the public and key stakeholders (including teachers, administrators, families, legislators, and policymakers) in each State or in each member State within a consortium about the assessments and for building support from the public and those stakeholders.

(f) *Technology approach.* The Secretary reviews each application to determine the extent to which the eligible applicant would use technology effectively to improve the quality, accessibility, cost-effectiveness, and efficiency of the proposed assessments. In determining the extent to which the eligible applicant is using technology effectively, we will consider——

(1) The description of, and rationale for, the ways in which technology will be used in assessment design, development, administration, scoring, and reporting; the types of technology to be used (including whether the technology is existing and commercially available or is being newly developed); and how other States or organizations can re-use in a cost-effective manner any technology platforms and technology components developed under this grant; and

(2) How technology-related implementation or deployment barriers will be addressed (e.g., issues relating to local access to internet-based assessments).

(g) *Project management.* The Secretary reviews each application to determine the extent to which the eligible applicant's project management plan will result in implementation of the proposed assessments on time, within budget, and in a manner that is financially sustainable over time. In determining the extent to which the project management plan has these attributes, we will consider——

(1) The project workplan and timeline, including, for each key deliverable (e.g., necessary procurements and any needed approvals for human subjects research, assessment, scoring and moderation system, professional development activities), the major milestones, deadlines, and entities responsible for execution;

(2) The approach to identifying, managing, and mitigating risks associated with the project;

(3) The extent to which the eligible applicant's budget is adequate to support the development of assessments that meet the requirements of the priority and includes costs that are reasonable in relation to the objectives, design, and significance of the proposed project and the number of students to be served;

(4) For each applicant State or for each member State within a consortium, the estimated costs for the ongoing administration, maintenance, and enhancement of the operational assessments after the end of the project period for the grant and a plan for how the State will fund the assessments over time (including by allocating to the assessments funds for existing State or local assessments that will be replaced by the new assessments); and

(5) The quality and commitment of the personnel who will carry out the proposed project, including the qualifications, relevant training and experience of the project director and other key project personnel, and the extent to which the time commitments of the project director and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

Final Priorities, Requirements, Definitions, and Selection Criteria:

We will announce the final priorities, requirements, definitions, and selection criteria in a notice in the **Federal Register**. We will determine the final priorities, requirements, definitions, and selection criteria after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use one or more of these proposed priorities, requirements, definitions, and selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Order 12866: Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and therefore subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities in a material way (also referred to as an "economically significant" rule); (2) create serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or

the principles set forth in the Executive Order. The Secretary has determined that this regulatory action is not significant under section 3(f) of the Executive Order.

This notice has been reviewed in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this proposed regulatory action.

The potential costs associated with this proposed regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of this proposed regulatory action, we have determined that the benefits of the proposed priorities, requirements, definitions, and selection criteria justify the costs.

More specifically, Title I, Part A of the ESEA requires States to annually assess the English language proficiency of English learners. The English language proficiency assessment systems to be developed under the proposed priority would be available for use by multiple States and could be used by States to meet their obligations under Title I, Part A. In addition, the requirements that the assessments be based on a set of English language proficiency standards held by the applicant State and, if the applicant applies as part of a consortium, held in common by all States in the consortium, that correspond to a common set of college- and career-ready standards in English language arts and mathematics would result in States that adopt the assessments being able to collect comparable data regarding the English language proficiency of their English learners. The proposed selection criteria would help ensure that the assessments developed by grantees are of high quality, meet relevant technical standards, and align with other assessment work funded by the Department. The proposed priority for consortia would encourage States to work together on developing assessments and other assessment-related instruments rather than developing or using separate assessments, thus creating cost efficiencies.

We have determined, also, that this proposed regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism. The Executive Order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance. This document provides notification of our specific plans regarding this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., Braille, large print, audiotape, or computer diskette) on request to the contact persons listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.*

To use PDF you must have Adobe Acrobat Reader, which is available free at this site. If you have questions about using PDF, call the U.S. Government Printing Office (GPO), toll free, at 1–888–293–6498; or in the Washington, DC, area at (202) 512–1530.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Catalog of Federal Domestic Assistance (CFDA) Number: 84.368A.

Dated: January 4, 2011.

Thelma Meléndez de Santa Ana,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2011–130 Filed 1–6–11; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP11–51–000]

CenterPoint Energy-Mississippi River Transmission Corporation; Notice of Application

December 29, 2010.

Take notice that on December 15, 2010, CenterPoint Energy-Mississippi River Transmission Corporation (MRT), 1111 Louisiana Street, Houston, Texas 77002–5231, filed in Docket No. CP11–51–000, an application pursuant to section 7(c) of the Natural Gas Act requesting authorization to reclassify approximately 1.2 billion cubic feet (Bcf) of cushion gas to working gas in the East and West Unionville Storage Fields located in Lincoln Parish, Louisiana. MRT states that the Inventory Verification Study disclosed a difference of approximately 1.2 Bcf less cushion gas than the accounting records. MRT avers that the differences were due to surface measurement and valve leakage. MRT affirms that no customer service will be impacted as a result of the reclassification, all as more fully set forth in the application, which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Lawrence O. Thomas, Sr. Director-Rate & Regulatory, CenterPoint Energy Mississippi River Transmission Corporation, P.O. Box 21734, Shreveport, Louisiana 71151, telephone No. (318) 429–2804, facsimile No. (318) 429–3133, and e-mail: *larry.thomas@centerpointenergy.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the

Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: January 19, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–47 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 349–168; 2407–134]

Alabama Power Company; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

December 30, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a: *Application Type:* Request for drought-based temporary variance of the Martin Project rule curve and minimum flow releases at the Yates and Thurlow Project.

b: *Project Nos.:* 349–168 and 2407–134.

c: *Date Filed:* November 30, 2010.

d: *Applicant:* Alabama Power Company.

e: *Name of Project:* Martin Hydroelectric Project (P–349) and Yates and Thurlow Hydroelectric Project (P–2407).

f: *Location:* The Martin Dam Project is located on the Tallapoosa River in the counties of Coosa, Elmore, and Tallapoosa, Alabama. The Yates and Thurlow Project is located on the Tallapoosa River in the counties of Elmore and Tallapoosa, Alabama.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h: *Applicant Contact:* Mr. Jason Powers, Alabama Power Company, 600 18th Street North, Birmingham, Alabama 35203–8180, Tel: (205) 257–4070.

i. *FERC Contact:* Christopher Chaney, (202) 502–6778, *christopher.chaney@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests: 15 days from the issuance date of this notice.

All documents may be filed electronically via the Internet. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* Alabama Power is requesting a drought-based temporary variance to the Martin Project rule curve. The rule curve variance would be in effect from the date of Commission approval to March 1, 2011, and would allow the licensee to maintain the winter pool elevation 3 feet higher than normal, at elevation 483 feet instead of elevation 480 feet. In association with the Martin rule curve variance, the minimum flows from the Thurlow reservoir (P–2407) would be temporarily modified as follows until May 1, 2011: (1) When downstream Alabama River flows are reduced 10%, discharge would be the greater of ½ Yates inflow or 2 times inflow at the upstream Heflin gage; (2) when downstream Alabama River flows are reduced 20%, the discharge would be 350 cfs; and (3) if Alabama River flows are reduced to 2,000 dsf, the discharge would be 400 cfs.

l. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding

the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Any filings must bear in all capital letters the title "COMMENTS," "PROTEST," or "MOTION TO INTERVENE," as applicable, and the Project Number of the particular application to which the filing refers. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–48 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Intent To Prepare an Environmental Assessment for the Proposed Northeast Supply Diversification Project and Ellisburg to Craigs Project, and Request for Comments on Environmental Issues

December 30, 2010.

Tennessee Gas Pipeline Company.	Docket No. CP11–30–000
Dominion Transmission, Inc.	Docket No. CP11–41–000

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of two related projects proposed by Tennessee Gas Pipeline Company (TGP) and Dominion Transmission, Inc. (DTI). TGP's Northeast Supply Diversification Project would involve construction and operation of facilities in Tioga and Bradford Counties, Pennsylvania and in Niagara, Erie, and Livingston Counties, New York. DTI's Ellisburg to Craigs Project would involve construction and operation of facilities in Livingston and Wyoming Counties, New York and Potter County, Pennsylvania. This EA will be used by the Commission in its decision-making process to determine whether the projects are in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues need to be evaluated in the EA. Please note that the scoping period will close on January 31, 2011.

This notice is being sent to the Commission's current environmental mailing list for these projects. State and local government representatives are asked to notify their constituents of these planned projects and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, you may be contacted by a pipeline company representative about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the projects are approved by the Commission, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?" was attached to the project notice TGP and DTI provided to landowners. This fact sheet addresses a number of typically-asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*http://www.ferc.gov*).

Summary of the Proposed Projects

TGP proposes to construct and operate 6.8 miles of natural gas pipeline loop,[1] modifications at an existing meter station and compressor station, and other appurtenant facilities. The Northeast Supply Diversification Project would provide TGP with up to 150,000 dekatherms (Dth/d) per day of leased capacity from DTI. According to TGP and DTI, their projects would increase natural gas delivery capacity in the northeast region of the U.S.

The Northeast Supply Diversification Project would consist of the following facilities:

- 6.8 miles of 30-inch-diameter natural gas pipeline in Tioga and Bradford Counties, Pennsylvania;
- Piping/valve modifications at existing Compressor Station 230C in Niagara County, New York;
- A new pig[2] receiver at existing Compressor Station 317 in Bradford County, Pennsylvania;
- Modifications at five existing meter stations in Erie and Niagara Counties, New York; and
- Tap replacement at an existing interconnection between TGP's 200 Line and DTI's pipeline system in Livingston County, New York.

DTI proposes to construct compression, metering, pipeline, and pressure regulation facilities to provide the proposed leased capacity to TGP. The Ellisburg to Craigs Project would consist of the following facilities:

- A new 10,800 horsepower compressor station in Wyoming County, New York;

[1] A pipeline loop is constructed parallel to an existing pipeline to increase capacity.

[2] A "pig" is a tool that is inserted into and moves through the pipeline, and is used for cleaning the pipeline, internal inspections, or other purposes.

• Replacement of 2,875 feet of 8-inch-diameter pipeline with 16-inch-diameter pipeline and a new meter station in Livingston County, New York; and

• Construction of new pressure regulation facilities at existing meter stations in Livingston County, New York and Potter County, Pennsylvania.

The general locations of the projects' facilities are shown in appendix 1.[3]

Land Requirements for Construction

TGP's project would disturb approximately 111 acres of land for the aboveground facilities and the pipeline. Following construction, about 51 acres would be maintained for permanent operation of the project's facilities; the remaining acreage would be restored and allowed to revert to former uses. The entire proposed pipeline route parallels TGP's existing pipeline right-of-way.

DTI's project would disturb approximately 38 acres of land for the aboveground facilities and the pipeline. Following construction, about 11 acres would be maintained for permanent operation of the project's facilities; the remaining acreage would be restored and allowed to revert to former uses. The aboveground facilities would be constructed adjacent to existing aboveground facilities owned by DTI. The pipeline replacement would involve replacing the existing pipeline with a larger diameter pipeline in the same right-of-way.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [4] to discover and address concerns the public may have about proposals. This process is referred to as "scoping". The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. All comments received will be considered during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed projects under these general headings:

• Geology and soils;
• Land use;
• Water resources, fisheries, and wetlands;
• Cultural resources;
• Vegetation and wildlife;
• Air quality and noise;
• Endangered and threatened species; and
• Public safety.

We will also evaluate reasonable alternatives to the proposed projects or portions of the projects, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will be presented in the EA. The EA will be placed in the public record and, depending on the comments received during the scoping process, may be published and distributed to the public. A comment period will be allotted if the EA is published for review. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure your comments are considered, please carefully follow the instructions in the Public Participation section below.

With this notice, we are asking agencies with jurisdiction and/or special expertise with respect to environmental issues to formally cooperate with us in the preparation of the EA. These agencies may choose to participate once they have evaluated the proposals relative to their responsibilities. Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice. Currently, the New York Department of Agriculture and Markets has expressed its intention to participate as a cooperating agency in the preparation of the EA.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with applicable State Historic Preservation Offices (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the projects' potential effects on historic properties.[5] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs as the projects are further developed. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for these projects will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the projects. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that they will be received in Washington, DC on or before January 31, 2011.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the project docket number (CP11–30–000 and CP11–41–000) with your submission. The Commission encourages electronic filing of comments and has expert eFiling staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You may file your comments electronically by using the *eComment* feature, which is located on the Commission's Web site at *http://www.ferc.gov* under the link to *Documents and Filings.* An eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments electronically by using the *eFiling* feature, which is located on the Commission's website at *http://www.ferc.gov* under the link to *Documents and Filings.* With eFiling you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "*eRegister.*" You will be

[3] The appendices referenced in this notice are not being printed in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *http://www.ferc.gov* using the link called "eLibrary" or from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[4] "We", "us", and "our" refer to the environmental staff of the Commission's Office of Energy Projects.

[5] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Historic properties are defined in those regulations as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register for Historic Places.

asked to select the type of filing you are making. A comment on a particular project is considered a "Comment on a Filing"; or

(3) You may file a paper copy of your comments at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the projects. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed projects.

If the EA is published for distribution, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an "intervenor" which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are included in the User's Guide under the "e-filing" link on the Commission's Web site.

Additional Information

Additional information about the projects is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *http://www.ferc.gov* using the "eLibrary" link. Click on the eLibrary link, click on "General Search" and enter the docket number, excluding the last three digits in the Docket Number field (i.e., CP11–30 or CP11–41). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *http://www.ferc.gov/esubscribenow.htm.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–46 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12576–004]

CRD Hydroelectric LLC, Iowa; Notice of Availability of Environmental Assessment

December 23, 2010.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission (Commission) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47879), the Office of Energy Projects has reviewed the application for an original license for the Red Rock Hydroelectric Project (FERC Project No. 12576–004), to be located on the Des Moines River, in Marion County, Iowa, at the U.S. Army Corps of Engineers' Red Rock Dam.

Staff prepared an environmental assessment (EA), which analyzes the potential environmental effects of licensing the project, and concludes that licensing the project, with appropriate environmental protection measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* toll-free at 1–866–208–3676, or for TTY, 202–502–8659.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. Comments may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *http://www.ferc.gov/doc-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

For further information, contact Lesley Kordella at (202) 502–6406 or by e-mail at *Lesley.Kordella@ferc.gov.*

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–45 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13123–002—California]

Eagle Crest Energy Company; Notice of Availability of the Draft Environmental Impact Statement for the Eagle Mountain Pumped Storage Hydroelectric Project and Notice of Public Meetings

December 23, 2010.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission (Commission or FERC) regulations contained in the Code of Federal Regulations (CFR) (18 CFR part 380 [FERC Order No. 486, 52 FR 47897]), the Office of Energy Projects has reviewed the application for license for the Eagle Mountain Pumped Storage Hydroelectric Project (FERC No. 13123), located on the site of the inactive Eagle Mountain mine in Riverside County, California, near the town of Desert Center and prepared a draft environmental impact statement (EIS) for the project. The project would occupy 1,059.26 acres of federal lands administered by the U.S. Bureau of Land Management and 1,162 acres of private land owned by Kaiser Eagle Mountain, LLC.

The draft EIS contains staff's analysis of the applicant's proposal and the alternatives for a licensee for the Eagle Mountain Project. The draft EIS documents the views of governmental agencies, non-governmental organizations, affected Indian tribes, the public, the license applicant, and Commission staff.

A copy of the draft EIS is available for review at the Commission or may be viewed on the Commission's website at *http://www.ferc.gov*, using the "e-Library" link. Enter the docket number, excluding the last three digits, to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

All comments must be filed by Monday, February 28, 2011, and should reference Project No. 13123–002. Comments may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text-only comments, click on "eComment." For assistance, please contact FERC Online Support. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

Anyone may intervene in this proceeding based on this draft EIS (18 CFR 380.10). You must file your request to intervene as specified above.[1] You do not need intervenor status to have your comments considered.

In addition to or in lieu of sending written comments, you are invited to attend a public meeting that will be held to receive comments on the draft EIS. The time and location of the meeting is as follows:

Daytime Meeting

Date: February 3, 2011.
Time: 1 p.m.
Place: University of California at Riverside, Palm Desert Graduate Center.
Address: 75–080 Frank Sinatra Drive, Room B114/117, Palm Desert, California 92211.

Evening Meeting

Date: February 3, 2011,
Time: 7 p.m.–10 p.m.
Place: University of California at Riverside, Palm Desert Graduate Center.
Address: 75–080 Frank Sinatra Drive, Room B200, Palm Desert, California 92211.

At these meetings, resource agency personnel and other interested persons will have the opportunity to provide oral and written comments and recommendations regarding the draft EIS. The meetings will be recorded by a court reporter, and all statements (verbal and written) will become part of the Commission's public record for the project. This meeting is posted on the Commission's calendar located at *http://www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

For further information, please contact Kenneth Hogan at (202) 502–8434 or at *kenneth.hogan@ferc.gov.*

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–49 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

[1] Interventions may also be filed electronically via the Internet in lieu of paper. See the previous discussion on filing comments electronically.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AC11–19–000]

T.W. Phillips Pipeline Corp.; Notice of Filing

December 30, 2010.

Take notice that on December 17, 2010, T.W. Phillips Pipeline Corp. submitted a request for a waiver of the reporting requirement to file the FERC Form 2–A for 2010 and a waiver of the reporting requirement to file the FERC Form 3–Q for the first, second, and third quarters of 2011.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: January 31, 2011.

Kimberly Bose,

Secretary.

[FR Doc. 2011–39 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ11–6–000]

City of Anaheim, CA; Notice of Filing

December 30, 2010.

Take notice that on December 17, 2010, the City of Anaheim, California (Anaheim) filed its annual revision to its Transmission Revenue Balancing Account Adjustment, consistent with its Transmission Owner Tariff filed in Docket No. EL03–15–000, and the California Independent System Operator Corporation Tariff.

Anaheim also requests any necessary waivers by the Commission to allow its filing to be accepted for filing and approved by the Commission to become effective as of January 1, 2011.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 pm Eastern Time on January 18, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–40 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ11–9–000]

City of Pasadena, CA; Notice of Filing

December 30, 2010.

Take notice that on December 22, 2010, the City of Pasadena, California (Pasadena) filed its annual revisions to is Transmission Revenue Balancing Account Adjustment and a related modification to Appendix I to Pasadena's Transmission Owner Tariff (TO), consistent with its TO filed in docket No. EL03–21–000 and the California Independent System Operator Corporation Electric Tariff.

Pasadena also requests any necessary waivers by the Commission to allow this filing to be accepted for filing and approved by the Commission to become effective as of January 1, 2011.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 pm Eastern Time on January 21, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–43 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ11–7–000]

City of Riverside, CA; Notice of Filing

December 30, 2010.

Take notice that on December 20, 2010, the City of Riverside, California (Riverside) filed a Petition for Declaratory Order, Request for waiver of Sixty-day Notice Requirement, and Request for Waiver of Filing Fee, pursuant to the terms of its Transmission Owner Tariff, which provide for an annual update the cost of its Existing Transmission Contracts (ETC) with Southern California Edison Company and a true-up of Riverside's ETC cost for the prior year.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for

review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 19, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–41 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ11–10–000]

City of Azusa, CA; Notice of Filing

December 30, 2010.

Take notice that on December 23, 2010, the City of Azusa, California (Azusa) filed its annual revisions to is Transmission Revenue Balancing Account Adjustment and a related modification to Appendix I to Azusa's Transmission Owner Tariff (TO), consistent with its TO filed in Docket No. EL03–21–000 and the California Independent System Operator Corporation Electric Tariff.

Azusa also requests any necessary waivers by the Commission to allow this filing to be accepted for filing and approved by the Commission to become effective as of January 1, 2011.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 24, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–44 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ11–8–000]

City of Banning, CA; Notice of Filing

December 30, 2010.

Take notice that on December 22, 2010, the City of Banning, California (Banning) filed its annual revisions to is Transmission Revenue Balancing Account Adjustment and a related modification to Appendix I to Banning's Transmission Owner Tariff (TO) and an update of the notification of Appendix II to Banning's TO Tariff, consistent with its TO filed in docket No. EL03–21–000 and the California Independent System Operator Corporation Electric Tariff.

Banning also requests any necessary waivers by the Commission to allow this filing to be accepted for filing and approved by the Commission to become effective as of January 1, 2011.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 21, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–42 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER11–2497–000]

Great American Power, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

December 23, 2010.

This is a supplemental notice in the above-referenced proceeding of Great American Power, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is January 12, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–38 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR09–25–003]

Crosstex North Texas Pipeline, L.P.; Notice of Motion for Extension of Rate Case Filing Deadline

December 30, 2010.

Take notice that on December 27, 2010, Crosstex North Texas Pipeline, L.P. (Crosstex North Texas) filed a request for an extension consistent with the Commission's revised policy of periodic review from a triennial to a five year period. The Commission in Order No. 735 modified its policy concerning periodic reviews of rates charges by section 311 and Hinshaw pipelines to extend the cycle for such reviews from three to five years.[1]

Therefore, Crosstex North Texas requests that the date for its next rate filing be extended to April 17, 2014, which is five years from the date of Crosstex North Texas' most recent rate filing with this Commission.

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on Monday, January 10, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–36 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

[1] Contract Reporting Requirements of Intrastate Natural Gas Companies, Order No. 735, 131 FERC ¶61,150 (May 20, 2010).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR09–19–003]

Crosstex LIG, LLC; Notice of Motion for Extension of Rate Case Filing Deadline

December 30, 2010.

Take notice that on December 27, 2010, Crosstex LIG, LLC (Crosstex LIG) filed a request for an extension consistent with the Commission's revised policy of periodic review from a triennial to a five year period. The Commission in Order No. 735 modified its policy concerning periodic reviews of rates charges by section 311 and Hinshaw pipelines to extend the cycle for such reviews from three to five years.[1]

Therefore, Crosstex LIG requests that the date for its next rate filing be extended to March 3, 2014, which is five years from the date of Crosstex LIG's most recent rate filing with this Commission.

Any person desiring to participate in this rate proceeding must file a motion to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the

[1] Contract Reporting Requirements of Intrastate Natural Gas Companies, Order No. 735, 131 FERC ¶ 61,150 (May 20, 2010).

"eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on Monday, January 10, 2011

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–50 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL11–13–000]

Atlantic Grid Operations A LLC, Atlantic Grid Operations B LLC, Atlantic Grid Operations C LLC, Atlantic Grid Operations D LLC and Atlantic Grid Operations E LLC; Notice of Petition for Declaratory Order

December 23, 2010.

Take notice that on December 20, 2010, pursuant sections 205 and 219 of the Federal Power Act, Rule 207 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207, and Order No. 679,[1] Atlantic Grid Operations A LLC, Atlantic Grid Operations B LLC, Atlantic Grid Operations C LLC, Atlantic Grid Operations D LLC, and Atlantic Grid Operations E LLC filed a Petition for Declaratory Order requesting that the Commission grant their request for incentive rate treatment and approve a return on equity for their investments in the Atlantic Wind Connection project.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 19, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–37 Filed 1–6–11; 8:45 am]

BILLING CODE 6717–01–P

[1] *Promoting Transmission Investment through Pricing Reform,* Order No. 679, 2006–2007 FERC Stats. & Regs., Regs. Preambles ¶ 31,222, *order on reh'g,* Order No. 679–A, 2006–2007 FERC Stats. & Regs., Regs. Preambles ¶ 31,236 (2006), *order on reh'g,* 119 FERC ¶ 61,062 (2007).

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9249–7]

Agency Information Collection Activities OMB Responses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the Office of Management and Budget (OMB) responses to Agency Clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

FOR FURTHER INFORMATION CONTACT: Rick Westlund (202) 566–1682, or e-mail at *westlund.rick@epa.gov* and please refer to the appropriate EPA Information Collection Request (ICR) Number.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency Clearance Requests

OMB Approvals

EPA ICR Number 2300.07; Regulation to Establish Mandatory Reporting of Greenhouse Gases (Technical Correction); 40 CFR parts 86, 89, 90, 94, 98, 600, 1033, 1039, 1042, 1045, 1048, 1051, 1054 and 1065, was approved on 12/08/2010; OMB Number 2060–0629; expires on 11/30/2012; Approved without change.

EPA ICR Number 2396.01; Mandatory Reporting of Greenhouse Gases from Magnesium Production, Underground Coal Mines, Industrial Wastewater Treatment, and Industrial Waste Landfills (Final Rule); 40 CFR part 98, subparts T, FF, II, and TT, was approved on 12/09/2010; OMB Number 2060–0647; expires on 12/31/2013; Approved without change.

EPA ICR Number 2375.01; Implementation of Ambient Air Protocol Gas Verification Program (New Collection); 40 CFR part 58; was approved on 12/09/2010; OMB Number 2060–0648; expires on 12/31/2013; Approved without change.

EPA ICR Number 2236.03; 8-Hour Ozone National Ambient Air Quality Standard Implementation Rule (Renewal); 40 CFR 51.908, 51.910 and 51.912; was approved on 12/09/2010; OMB Number 2060–0594; expires on 12/31/2013; Approved without change.

EPA ICR Number 1593.08; Air Emission Standards for Tanks, Surface Impoundments and Containers; 40 CFR part 264, subpart CC and 40 CFR part 265, subpart CC, was approved on 12/15/2010; OMB Number 2060–0318; expires on 12/31/2013; Approved without change.

EPA ICR Number 2256.03; NESHAP for Acrylic/Modacrylic Fibers Prod., Carbon Black Prod., Chemical Mfg: Chromium Compounds, Flexible Polyurethane Foam Production/ Fabrication, Lead Acid Battery Mfg, Wood Preserving (Renewal); 40 CFR part 63, subparts A, LLLLLL, MMMMMM, NNNNNN, OOOOOO, PPPPPP and QQQQQQ; was approved on 12/15/2010; OMB Number 2060–0598; expires on 12/31/2013; Approved without change.

EPA ICR Number 1687.08; NESHAP for Aerospace Manufacturing and Rework Facilities; 40 CFR part 63, subparts A and GG; was approved on 12/15/2010; OMB Number 2060–0314; expires on 12/31/2013; Approved without change.

EPA ICR Number 1071.10; NSPS for Stationary Gas Turbines; 40 CFR part

60, subparts A and GG; was approved on 12/17/2010; OMB Number 2060–0028; expires on 12/31/2013; Approved with change.

EPA ICR Number 2376.02; Regulation to Establish Mandatory Reporting of Greenhouse Gases (Final Rule for Petroleum and Natural Gas, Subpart W); 40 CFR part 98, subpart W; was approved on 12/21/2010; OMB Number 2060–0651; expires on 12/31/2013; Approved without change.

EPA ICR Number 2372.02; Mandatory Reporting of Greenhouse Gases (Final Rule for Injection and Geological Sequestration of Carbon Dioxide); 40 CFR part 98, subparts RR and UU; was approved on 12/21/2010; OMB Number 2060–0649; expires on 12/31/2013; Approved without change.

EPA ICR Number 2373.02; Mandatory Reporting of Greenhouse Gases (Final Rule for Additional Sources of Fluorinated Greenhouse Gases); 40 CFR part 98, subparts I, L, DD, QQ, and SS; was approved on 12/21/2010; OMB Number 2060–0650; expires on 12/31/2013; Approved without change.

EPA ICR Number 2300.06; Regulation to Establish Mandatory Reporting of Greenhouse Gases (Reconsideration Package); 40 CFR parts 86, 89, 90, 94, 98, 600, 1033, 1039, 1042, 1045, 1048, 1051, 1054 and 1065, was approved on 12/21/2010; OMB Number 2060–0629; expires on 11/30/2012; Approved without change.

EPA ICR Number 2185.04; State Review Framework; 40 CFR 70.4, 123.41 and 271.17(a), was approved on 12/21/2010; OMB Number 2020–0031; expires on 12/31/2013; Approved without change.

EPA ICR Number 2212.03; Minority Business Enterprise/Woman Business Enterprise (MBE/WBE) Utilization under Federal Grants Cooperative Agreements and Interagency Agreements (Reinstatement); 40 CFR part 33; was approved on 12/21/2010; OMB Number 2090–0025; expires on 12/31/2013; Approved without change.

EPA ICR Number 2300.08; Regulation to Establish Mandatory Reporting of Greenhouse Gases (Reconsideration Package); 40 CFR parts 86, 89, 90, 94, 98, 600, 1033, 1039, 1042, 1045, 1048, 1051, 1054 and 1065, was approved on 12/22/2010; OMB Number 2060–0629; expires on 11/30/2012; Approved without change.

EPA ICR Number 1663.07; Compliance Assurance Monitoring Program; 40 CFR part 64; was approved on 12/30/2010; OMB Number 2060–0376; expires on 12/31/2013; Approved without change.

Comment Filed

EPA ICR Number 2394.01; Control of Greenhouse Gas Emissions from New Motor Vehicles: Proposed Heavy-Duty Engine and Vehicle Standards (Proposed Rule); in 40 CFR parts 86, 1036 and 1037 and 49 CFR parts 523, 534 and 535; OMB filed comment on 12/08/2010.

EPA ICR Number 2369.01; NSPS for Sewage Sludge Incinerators; in 40 CFR part 60, subpart LLLL; OMB filed comment on 12/15/2010.

EPA ICR Number 1611.08; NESHAP for Chromium Emissions from Hard and Decorative Chromium Electroplating and Chromium Anodizing Tanks; in 40 CFR part 63, subparts A and N; OMB filed comment on 12/15/2010.

EPA ICR Number 1679.08; NESHAP for Marine Tank Vessel Loading Operations; in 40 CFR part 63, subparts A and Y; OMB filed comment on 12/15/2010.

EPA ICR Number 2410.01; NESHAP for Group I Polymers and Resins; in 40 CFR part 63, subpart U; OMB filed comment on 12/15/2010.

EPA ICR Number 2403.01; EG for Sewage Sludge Incinerators; in 40 CFR part 60, subpart MMMM; OMB filed comment on 12/15/2010.

Dated: January 3, 2011.

John Moses,

Director, Collections Strategies Division.

[FR Doc. 2011–110 Filed 1–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–8993–5]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–1399 or *http://www.epa.gov/compliance/nepa/*

Weekly Receipt of Environmental Impact Statements Filed 12/27/2010 Through 12/31/2010 Pursuant to 40 CFR 1506.9.

Notice: In accordance with Section 309(a) of the Clean Air Act, EPA is required to make its comments on EISs issued by other Federal agencies public. Historically, EPA met this mandate by publishing weekly notices of availability of EPA comments, which includes a brief summary of EPA's comment letters, in the **Federal Register**. Since February 2008, EPA has included its comment letters on EISs on its Web site at: *http://www.epa.gov/compliance/nepa/eisdata.html.* Including the entire EIS comment letters on the Web site satisfies the Section 309(a) requirement to make EPA's comments on EISs available to the public. Accordingly, on March 31, 2010, EPA discontinued the publication of the notice of availability of EPA comments in the **Federal Register**.

EIS No. 20100482, Draft EIS, USACE, MO, Programmatic—Mechanical Creation and Maintenance of Emergent Sandbar Habitat in the Riverine Segments of the Upper Missouri River, To Support Least Tern and Piping Plover Populations, Implementation, MO, Comment Period Ends: 02/22/2011, Contact: Cynthia S. Upah, 402–995–2672. This document is available on the Internet at:

EIS No. 20100483, Final EIS, FHWA, MO, Rex Whitton Expressway Project, To Safely and Reliably Improve Personal and Freight Mobility, Reduce Traffic Congestion, US 50/63 (Rex Whitton Expressway, also Known as Whitton) Facility in Cole County, MO, Wait Period Ends: 02/07/2011, Contact: Peggy Casey, 573–636–7104.

EIS No. 20100484, Draft EIS, USFS, NM, Gila National Forest Travel Management Plan, Implementation, Silver City, NM, Comment Period Ends: 03/07/2011, Contact: Lisa Mizuno, 575–388–8267.

EIS No. 20100485, Final EIS, USFS, CA, Hi-Grouse Project, Proposes to Treat Ponderosa Pine and Mixed Conifer Stands to Improve Long-Term Forest Health and Reduce Fuels within the Goosenest Adaptive Management Area, Goosenest Ranger District, Klamath National Forest, Siskiyou Co, CA, Wait Period Ends: 02/02/2011, Contact: Wendy Coats, 530–841–4470.

Dated: January 4, 2011.

Robert W. Hargrove,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2011–112 Filed 1–6–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9247–7]

Operating Industries, Inc., Superfund Site, Monterey Park, CA; Notice of Proposed CERCLA Administrative De Minimis Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for comment.

SUMMARY: In accordance with Section 122(i)(1) of the Comprehensive

Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9622(i) and Section 7003(d) of the Resource Conservation and Recovery Act, as amended (RCRA), 42 U.S.C. 6973, notice is hereby given of a proposed administrative settlement with 275 *de minimis* settling parties for recovery of response costs concerning the Operating Industries, Inc., Superfund Site in Monterey Park, California. The settlement is entered into pursuant to Section 122(g) of CERCLA, 42 U.S.C. 9622(g) and it requires the settling parties to pay $17,027,998 to the United States Environmental Protection Agency (Agency). The settlement includes a covenant not to sue the settling parties pursuant to Sections 106 or 107(a) of CERCLA, 42 U.S.C. 9607(a) or 9606, and Section 7003(d) of RCRA, 42 U.S.C. 6973. For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate. The Agency's response to any comments received will be available for public inspection at 75 Hawthorne Street, San Francisco, CA 94105.

DATES: Pursuant to Section 122(i)(1) of CERCLA and Section 7003(d) of RCRA, EPA will receive written comments relating to this proposed settlement on or before February 7, 2011. Pursuant to Section 7003(d) of RCRA, commenters may request an opportunity for a public meeting in the affected area. If EPA receives a request for a public meeting within thirty (30) days following the publication of this Notice, EPA will hold a public meeting at a date and location to be determined.

ADDRESSES: The proposed settlement is available for public inspection at EPA Region IX, 75 Hawthorne Street, San Francisco, California. A copy of the proposed settlement may be obtained from Keith Olinger, EPA Region IX, 75 Hawthorne Street, SFD–7–5, San Francisco, CA 94105, telephone number 415–972–3125. Comments should reference the Operating Industries, Inc., Superfund Site in Monterey Park, California and EPA Docket No. 2010–04 and should be addressed to Keith Olinger at the above address.

FOR FURTHER INFORMATION CONTACT: Janet Magnuson, Assistant Regional Counsel (ORC–3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; phone: (415) 972–3887; fax: (415) 947–3570; e-mail: *magnuson.janet@epa.gov*

Dated: January 7, 2010.

Jane Diamond,

Director, Superfund Division, U.S. EPA, Region IX.

Parties to the Proposed Settlement: ABM Janitorial Services, Inc., as successor-in-interest to American Building Maintenance Company, Agrex, Inc., Agri-Chemical & Supply, Inc., Air System Components, Inc. (fka Lau Industries, Inc.) and Ruskin Company, Lau Division, Akzo Nobel Coatings, Inc. (as successor to Reliance Universal, Inc.), Al Asher & Sons Inc., Al Larson Boat Shop, Alcan Packaging Food and Tobacco Inc., Alhambra Valley Properties, Alladin Plastics, Inc., Allan Aircraft Supply Co., LLC, Allegiance Corporation, Allen Telecom, Inc., Angelica Corporation, Aramark Uniform & Career Apparel, LLC, Arrow Electronics, Inc., Associated Plating Company, Astro Pak Corporation, Authentic Specialty Foods, Inc., dba La Victoria Foods, Avalon Glass & Mirror Co., Avery Dennison Corporation, Aviall, Inc., Axis Petroleum Company, B–J Management, Inc., Baker Hughes Incorporated, Baker Hughes Oilfield Operations, Inc., BakerCorp, Baldor Electric Company, as successor by merger to Reliance Electric Company (fka Reliance Electric Industrial Company), Beazer East, Inc., Bell Industries, Inc., Beren Corporation, Beylik Drilling, Inc., Big Penny Car Wash General Partnership, Bimbo Bakeries USA, Inc., Bimbo Foods, Inc., successor-in-interest to George Weston Bakeries, Inc., Blount, Inc., successor-in-interest to Omark Industries, Inc., Bodycote Thermal Processing, Inc., Bragg Investment Company, Inc., Brea Olinda Unified School District, Bridgford Foods Corporation, Bristow Group Inc., Burmar Metal Finishing Corp., dba Barron Anodizing, Cackle Fresh Egg Farms, Inc., Califone International, Inc., California Amforge Corp., California Department of Transportation, Cargill, Incorporated, Carrier Corporation, Carrier Service, Inc., Casa De Cadillac, Cast-Rite International, Inc. and Cast-Rite Corporation, Castrol Industrial North America, Inc., Cenveo Corporation, Certance, LLC, Certified Caterers Corp., Chem Arrow Corporation International, City of Long Beach, City of Paramount, City of Santa Monica, Clean Harbors, Inc., and its operating subsidiaries, and in its capacity as indemnitor for Safety Kleen (Los Angeles), Inc., Clear Channel Outdoor, Inc., Closetmaid Corporation, Collins Food Service, Inc., ConAgra Grocery Products Company, LLC, ConocoPhillips Company, Continuous Coating Corporation, Coscol Petroleum Corporation, Cosho, Inc., successor of Barr, Inc., County Sanitation District No. 2 of Los Angeles County, Crowley Marine Services, Inc., Cunico Corporation, Cushman & Wakefield of California, Inc., Dal-Tile International, Inc., Dart Transportation Service, Del Monte Corporation, Dexter 1994, LLC, Dickies Industrial Services, Inc., DII Industries, LLC, Dilo, Inc., Dolores Canning Co. Inc., Dominguez Properties, Dowell Schlumberger, Inc., Downey Glass Co. Incorporated, Dyanco, Inc., Econolite Control Products, Inc., Ed Anglemyer & Sons, Inc., Ed Butts Ford, Inc., El Monte Plastics, Inc., El Paso Energy E.S.T. Company as Trustee for EPEC Oil Company Liquidating Trust, Elixir Industries, EPEC Polymers, Inc., Essex Chemical Corporation, Evans Tank Line, Inc., Exxon Mobil Corporation, First Student, Inc. and First Transit, Inc., as successors to Laidlaw Transit, Inc. and Laidlaw Transit Services, Inc., Food 4 Less of Southern California, Inc., Freeport-McMoran Corporation, Gannett Flagstaff Broadcasting, Inc., Gasket Manufacturing Co., GCG Corporation, General Steamship International, Ltd., Genlyte Thomas Group LLC, as successor-in-interest to Lightolier, Inc., Geo Drilling Fluids, Inc., George O. Ladner, Jr., Trustee, Trepanier Trust, Georgia-Pacific, LLC, on behalf of Unisource Worldwide, Inc., Gillespie Furniture Co., Glendale Adventist Medical Center, Goodrich Corporation, Goulds Pumps, Inc., Grand-Way Fabri-Graphics Inc., Grayson Service, Inc., H.B. Fuller Company, Hacienda Golf Club, Handy & Harman, Hanson Aggregates LLC, fka Hanson Aggregates West, Inc., Harbour Auto Spa, Haskel Hall, Inc., Helium Leak Testing, Inc., Hexcel Corporation, Hexion Specialty Chemical Co., Inc., fka Borden, Inc., Hillcrest Beverly Oil Corporation, Hollingsead International, Inc., Home Furnishing Acquisition Corporation, as successor to Hoyne Industries, Inc., Hood Corporation, Hosokawa Micron International Inc., Host Hotels & Resorts, Inc., Howard Supply Company, Hugh J. Resins, Inc., IMO Industries, Inc., ITT Industries, Inc., nka ITT Corporation, J. C. Garet Inc., J. Colavin & Son, Inc., Jacob Stern & Sons, Inc., Jas. D. Easton, Inc., John W. Potter, Inc., Joslyn Manufacturing Company, LLC, Kao Brands Company, Kellogg Brown & Root, Inc., Kenneth W. Jones and Coastal Drilling Company, Key Energy Services, Inc., Kruse and Son, Inc., L & N Uniform Supply, LLC, L–3 Services,

Inc., La Cienega Partners Limited Partnership, Lakeside Car Wash, Latshaw Enterprises, Inc., Lennox Car Wash, Linde, LLC, Lonesome Dove Petroleum Co., Louisiana-Pacific Corporation, LSG Sky Chefs USA, Inc., as successor to Caterair International Corporation, Lynco Grinding Company, Inc., M & R Industries, Inc., Mac's Radiator Service, Manufacturers Service, Inc., Marco Manufacturing, Inc., Maruichi American Corp., Master Products Manufacturing Company, Inc., Master Protection Corporation, Matson Terminals, Inc., McGregor II, LLC, McKesson Corporation, Metal Improvement Company, LLC, Montebello Car Wash, Inc., Mortell Company, Morton International, LLC, successor-in-interest to Morton International, Inc., MPC Industrial Products, Inc., by Paul Queyrel, President, National Plant Services, Inc., Nellcor Puritan Bennett, LLC, Nestle Waters North America Inc. for Arrowhead Drinking Water Co., New Bristol Farms, Inc., Northrop Grumman Guidance and Electronics Company, Inc., Northrop Grumman Systems Corporation (successor to Lucas Western), O'Donnell Oil Company, nka O'Donnell Oil, LLC, Olin Corporation, Oltmans Construction Co., Optical Coating Laboratory, Inc., Orange County Water District, Pacific Bell Telephone Company, Pacific Towboat & Salvage Co., Pactiv Corporation/A&E Plastics, Inc., Pagengruppen AB, Palisades Gas and Wash, Inc., Palmcrest North Convalescent Hospital, Paramount Interests, Inc., Parker-Hannifin Corporation, as indemnitor for Steel Forming Inc. dba Commercial Metal Forming, fka Orange County Metal Works aka Orange County Machine Works, PCC Technical Industries, Inc., Penske Truck Leasing Co., L.P., Pentrate Metal Processing, Pioneer Natural Resources Company, PolyOne Corporation, Port of Long Beach, Long Beach Harbor Department, Presbyterian Intercommunity Hospital, Inc., Pro-Line Corp.

Quemetco, Inc., R.H.S. Carpet Mill, Inc., R.R. Donnelley & Sons Company, Rangers Die Casting Co., Ray's Car Wash, Raytheon Company, Republic Services, Inc. (two generators), Ringsby Truck Lines, Inc., Riviera Rolls Royce, Robert Ruehman, Inc., Royalweve Carpet Mills, Inc. and Norman A. Subotky, San Gabriel Valley Water Company, Sanitek Products, Inc., Santa Fe Braun, Inc., Scope Products, Inc., Scott Technologies, Inc., Seattle Systems, Inc. and Trulife, Inc., Shepherd Financial Services, LLC, Shuttle Bus Leasing, Siemens Water Technologies Corp., Sika Corporation, Southern California Drum Co., Southwest Trails, Spectrolab, Inc., SSA Marine, Inc., Standridge Granite Corporation, Standun, Inc., Sullair Corporation, Sunkist Growers, Inc., Sunset Pipeline and Terminalling, Inc., SVG, Inc., SWECO/Emerson Electric Co., TCI Pacific Communications Inc., TDY Industries, Inc., Teberg Oil Company, Texaco, Inc., The Boeing Company, The Dow Chemical Company, The Goodyear Tire & Rubber Company, The Hearst Corporation, The Nehms Company, Inc., The Valspar Corporation, The Wackeen Family Trust, as the distributee of the assets of Ronald Moran Cadillac, Inc., a dissolved California Corporation, Thomas & Betts Corporation, Thrifty Payless Inc., successor to Thrifty Corporation, Toko Line (U. S. A.), Ltd., Torrance Car Wash, Tri-J Metal Heat Treating Co., TRW Automotive, Inc., Tube City IMS Corporation, Tulip Corporation, Tyco Healthcare Group, LP, Union Development Financial, Inc., Union Pacific Railroad Company, Unisys Corporation, United Drill Bushing Corporation, United Rentals, Inc., United States Steel Corporation and its subsidiaries, Universal City Studios, LLLP, a Delaware limited liability limited partnership (fka Universal City Studios LP, Universal City Studios LLC, and Universal City Studios, Inc., and Universal Studios, Inc.), URS Corporation, Valero Energy Corporation for and on behalf of its subsidiaries and affiliated companies, Valley Metal Treating, Inc., Valley Presbyterian Hospital, Venture Shipping (Managers) Ltd., Virco Mfg. Corporation, Vista Paint Corp., Vista-Kraft, Inc., Wash Multifamily Laundry Systems, LLC, Waterman Supply Company, Inc., Wei-Chuan USA, Inc., West Chemical Products, Inc./Penetone Corp., Western Methods Machinery Corporation, Western Waste Industries, Williams Production RMT Company, Wilsey Bennett, Inc., Wilsonart International, Inc., Wolf Tank Lines, Inc., Young's Market Company, LLC, Younger Mfg. Co., Your Man Tours, Inc., Zeneca Inc., as successor-in-interest to Stuart Pharmaceutical Co.

[FR Doc. 2010–33283 Filed 1–6–11; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Sunshine Act; Regular Meeting

AGENCY: Farm Credit Administration.

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the regular meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on January 13, 2010, from 9 a.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Dale L. Aultman, Secretary to the Farm Credit Administration Board, (703) 883–4009, TTY (703) 883–4056.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. In order to increase the accessibility to Board meetings, persons requiring assistance should make arrangements in advance. The matters to be considered at the meeting are:

Open Session

A. Approval of Minutes

- December 9, 2010

B. New Business

- Auditor's Report on FCA Fiscal Year 2010/2009 Financial Statements

C. Reports

- Office of Examination Quarterly Report

Closed Session*

Reports

- Update on Office of Examination Oversight Activities

Dated: January 5, 2011.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

*Session Closed-Exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

[FR Doc. 2011–252 Filed 1–5–11; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

January 4, 2011.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–

3520), the Federal Communications Commission invites the general public and other Federal agencies to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before February 7, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or the Internet at *Nicholas_A._Fraser@omb.eop.gov;* and to the Federal Communications Commission's PRA mailbox (e-mail address: *PRA@fcc.gov.*). Include in the e-mail the OMB control number of the collection as shown in the **SUPPLEMENTARY INFORMATION** section below, or if there is no OMB control number, include the Title as shown in the **SUPPLEMENTARY INFORMATION** section. If you are unable to submit your comments by e-mail, contact he person listed below to make alternate arrangements.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-b.herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0809.

Title: Communications Assistance for Law Enforcement Act (CALEA).

Form No.: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 200 respondents; 285 responses.

Estimated Time per Response: 7.5–80 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in Public Law 103–414, Communications Assistance for Law Enforcement Act (CALEA), sections 105, 107(c), 109(b) and 301; 47 U.S.C. 1004, 1006(c), 1008(b) and 229.

Total Annual Burden: 3,475 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: Pursuant to section 0.457(g) of the Commission's rules, the information in the CALEA system security filings and petitions will not be made routinely available for public inspection. Section 107(c) and 109(b) filings are entitled to confidential treatment under the Freedom of Information Act (FOIA). The Commission has directed respondents to file their petitions under a general claim of confidential or proprietary protection, subject only to scrutiny by the Commission and the Attorney General who is consulted in section 107(c) adjudications and is a party to all section 109(b) adjudications.

Needs and Uses: The Commission will submit this expiring information collection (IC) to the OMB during this comment period. The Commission is seeking OMB approval for a revision to this existing IC. The Commission is reporting a decrease of 2,800 total annual burden hours for this IC. The decrease is due to removal of a recordkeeping burden estimate associated in 47 CFR 1.20004. This estimate has been eliminated by 1,655 hours because the nature and extent of the requirement is usual and customary. Telecommunications carriers must keep such records to demonstrate that they are in compliance with Federal and State wiretapping laws and regulations that have existing for the past 40 years.

The Communications Assistance for Law Enforcement Act (CALEA) requires: (a) telecommunications carriers to protect against unlawful interception of communications of their facilities by establishing policies and procedures to ensure security and integrity of those facilities and to maintain records of all interceptions of unlawful electronic surveillance, and (b) the FCC to prescribe CALEA implementing rules and to review the carriers' filings under section 301(b) and to order any deficiencies to be corrected. Information collections include mandatory system security filings, and voluntary extension of time and cost reimbursement petitions.

Marlene H. Dortch,

Secretary, Federal Communications Commission.

[FR Doc. 2011–123 Filed 1–6–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Submitted for Review and Approval to the Office of Management and Budget (OMB), Comments Requested

December 21, 2010.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and (e) ways to further reduce the information collection burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before February 7, 2011. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or the Internet at *Nicholas_A._Fraser@omb.eop.gov;* and to the Federal Communications Commission's PRA mailbox (e-mail address: *PRA@fcc.gov.*). Include in the e-mail the OMB control number of the collection as shown in the **SUPPLEMENTARY INFORMATION** section below, or if there is no OMB control number, include the Title as shown in the **SUPPLEMENTARY INFORMATION** section. If you are unable to submit your comments by e-mail, contact the person listed below to make alternate arrangements.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Judith B. Herman at 202–418–0214 or via the Internet at *Judith-b.herman@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1094.

Title: Sections 4.1 and 4.2, and Part 4 of the Commission's Rules Concerning Disruptions to Communications (NORS).

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions, and State, local or Tribal government.

Number of Respondents: 71 respondents; 139 responses.

Estimated Time per Response: 2 hours.

Frequency of Response: On occasion reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 154, 218, 219, 256, 301, 302, 303, 403 and 621.

Total Annual Burden: 19,738 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: In accordance with 47 CFR 4.2 of the Commission's rules, reports under Part 4 are presumed confidential.

Needs and Uses: The Commission will submit this expiring information collection (IC) to the OMB during this comment period. The Commission is seeking OMB approval for an extension (there are no changes to the reporting requirement). The Commission is reporting a significant increase of 10,100 total annual burden hours. This is due to a recalculation of our burden estimates and fewer respondents reporting information. The estimated number of respondents fluctuates because of the type of event to be reported and the location where it occurred.

In recognition of the critical need for rapid, full, and accurate information on service disruptions that could affect homeland security, public health and safety, as well as the economic well-being of our Nation, and in view of the increasing importance of non-wireline communications in the Nation's communications networks, and critical infrastructure, the Commission adopted rules requiring mandatory service disruptions reporting from all communications providers (cable, satellite, wireline and wireless) that provide voice and/or paging communications. As envisioned, the information collected pursuant to these rules has helped improve network reliability.

OMB Control Number: 3060–1139.

Title: Residential Fixed Broadband Services Testing and Measurement.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households and business or other for-profit.

Number of Respondents: 11,016 respondents; 11,016 responses.

Estimated Time per Response: The estimated time per response is 1 hour for respondents based on a 10 minute initial sign-up for the panel; 30 minutes to connect and install the hardware appliance; and two 10-minute contacts to be conducted by the vendor over the course of the study period. The 16 ISP partners participating in the study is estimated at 200 hours per respondent per partner for all participation activities.

Frequency of Response: Biennial reporting requirement and third party disclosure requirement.

Obligation to Respond: Voluntary. Statutory authority for this information collection is contained in the Broadband Data Improvement Act of 2008, Public Law 110–385, Stat 4096 § 103(c)(1).

Total Annual Burden: 14,200 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: This information collection affects individuals or households. However, the collection of personally identifiable information (PII) is not being collected, made available or accessible by the Commission but instead by third parties including SamKnows, a third party contractor and ISP Partners.

Nature and Extent of Confidentiality: No personally identifiable information (PII) will be transmitted to the Commission from the contractor as a matter of vendor policy. SamKnows maintains a series of administrative, technical, and physical safeguards to protect against the transmission of personally identifying information. At point of registration, individuals will be given full disclosure in a "privacy statement" highlighting what information will be collected. ISP Partners will receive personally identifying information about volunteers to confirm the validity of the information against their subscription records, but will be bound by a non-disclosure agreement that will maintain various administrative, technical and physical safeguards to protect the information and limit its use. ISP Partners will provide support to the testing program will likewise be bound to the same series of administrative, technical and physical safeguards developed by SamKnows. In addition, all third parties supporting the program directly will be bound by a "Code of Conduct" to ensure that all participate and act in good faith.

Needs and Uses: The Commission will submit this expiring information collection (IC) to the OMB during this comment period. The Commission is requesting OMB approval for an extension (no change in the reporting and/or third party disclosure requirements). There is no change in the Commission's burden estimates that were submitted and approved by OMB on October 4, 2010.

The Broadband Data Improvement Act of 2008, Public Law 110–385, Stat 4096 § 103(c)(1) directs the Commission to collect information on the type of technology used to provide broadband to consumers, the price of such services, actual transmission speeds, and the reasons for non-adoption of broadband service.

The collection of information is necessary to complete research done for the Broadband Plan on key consumer issues including transparency and actual speeds and performance of broadband service.

Marlene H. Dortch,

Secretary, Federal Communications Commission.

[FR Doc. 2011–124 Filed 1–6–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[AU Docket No. 10–248; DA 10–2298]

Auction of 700 MHz Band Licenses Scheduled for July 19, 2011; Comment Sought on Competitive Bidding Procedures for Auction 92

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document announces the auction of 16 licenses in the 698–806 MHz band (700 MHz Band). The auction, which is designated Auction 92, is scheduled to commence on July 19, 2011. This document also seeks comment on competitive bidding procedures for Auction 92.

DATES: Comments are due on or before January 12, 2011, and reply comments are due on or before January 27, 2011.

ADDRESSES: All filings related to procedures for Auction 92 must refer to AU Docket No. 10–248. The Wireless Telecommunications Bureau strongly encourages interested parties to file comments electronically, and requests that an additional copy of all comments and reply comments be submitted electronically to the following address: *auction92@fcc.gov.* Comments may be submitted by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Attn: WTB/ASAD, Office of the Secretary, Federal Communications Commission.
- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW–A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

FOR FURTHER INFORMATION CONTACT: *Wireless Telecommunications Bureau, Auctions and Spectrum Access Division:* For auction legal questions: Lynne Milne at (202) 418–0660; for general auction questions: Debbie Smith or Lisa Stover at (717) 338–2868. *Mobility Division:* for 700 MHz service rules questions: Michael Connelly (legal) or Keith Harper (technical) at (202) 418–0620.

SUPPLEMENTARY INFORMATION: This is a summary of the *Auction 92 Comment Public Notice* released on December 15, 2010. The complete text of the *Auction 92 Comment Public Notice,* including an attachment and related Commission documents, is available for public inspection and copying from 8 a.m. to 4:30 p.m. ET Monday through Thursday or from 8 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The *Auction 92 Comment Public Notice* and related Commission documents also may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc. (BCPI), 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 202–488–5300, fax 202–488–5563, or you may contact BCPI at its Web site: *http://www.BCPIWEB.com.* When ordering documents from BCPI, please provide the appropriate FCC document number, for example, DA 10–2298. The *Auction 92 Comment Public Notice* and related documents also are available on the Internet at the Commission's Web site: *http://wireless.fcc.gov/auctions/92/,* or by using the search function for AU Docket No. 10–248 on the ECFS Web page at *http://www.fcc.gov/cgb/ecfs/.*

I. Licenses in Auction 92

1. Auction 92 will offer a total of 16 licenses. These licenses were offered in Auction 73 and remained unsold or were licenses on which a winning bidder defaulted. A complete list of licenses offered in Auction 92 is available in Attachment A to the *Auction 92 Comment Public Notice.*

II. Due Diligence

2. Each potential bidder is solely responsible for investigating and evaluating all technical and marketplace factors that may have a bearing on the value of 700 MHz Band licenses that the potential bidder is seeking in this auction. The FCC makes no representations or warranties about the use of this spectrum for particular services. Each applicant should be aware that this FCC auction represents an opportunity to become an FCC licensee in the 700 MHz Band, subject to certain conditions and regulations. An FCC auction does not constitute an endorsement by the FCC of any particular service, technology, or product, nor does an FCC license constitute a guarantee of business success.

3. An applicant should perform its due diligence research and analysis before proceeding, as the applicant would with any new business venture. Each potential bidder should perform technical analyses and/or refresh any previous analyses to assure the applicant that, should the applicant be a winning bidder for any Auction 92 license, the applicant will be able to build and operate facilities that will fully comply with all current technical and legal requirements. Each applicant is strongly encouraged to inspect any prospective sites located in, or near, the geographic area for which the applicant plans to bid, and also to familiarize itself with the Commission's rules regarding the National Environmental Policy Act at 47 CFR Chapter 1, Part 1, Subpart I.

4. Each applicant is strongly encouraged to conduct its own research prior to Auction 92 in order to determine the existence of pending administrative, rulemaking, or judicial proceedings that might affect the applicant's decisions regarding participation in the auction.

5. Participants in Auction 92 are strongly encouraged to continue such research throughout the auction. The due diligence considerations mentioned in the *Auction 92 Comment Public Notice* do not comprise an exhaustive list of steps that should be undertaken prior to participating in this auction. As always, the burden is on the potential bidder to determine how much research to undertake, depending upon the specific facts and circumstances related to its interests.

III. Bureau Seeks Comment on Auction Procedures

6. Consistent with the provisions of 47 U.S.C. 309(j)(3), and to ensure that potential bidders have adequate time to familiarize themselves with the specific rules that will govern the day-to-day conduct of an auction, the Bureau seeks comment on the following issues relating to Auction 92.

A. Auction Structure

i. Simultaneous Multiple-Round Auction Design

7. The Bureau proposes to auction all licenses included in Auction 92 using the Commission's standard simultaneous multiple-round auction format. This type of auction offers every license for bid at the same time and consists of successive bidding rounds in which eligible bidders may place bids

on individual licenses. Typically, bidding remains open on all licenses until bidding stops on every license. The Bureau seeks comment on this proposal.

ii. Anonymous Bidding

8. In a number of recent auctions, the Commission has adopted procedures to limit the disclosure of certain bidder-specific information until after the auction. Consistent with that practice, the Bureau proposes to conduct Auction 92 using certain procedures for limited information disclosure, or anonymous bidding. Specifically, the Bureau proposes to withhold, until after the close of bidding, public release of: (1) Bidders' license selections on their short-form applications (FCC Form 175); (2) the amounts of bidders' upfront payments and bidding eligibility; and (3) information that may reveal the identities of bidders placing bids and taking other bidding-related actions.

9. Under these proposed limited information procedures, the amount of every bid placed and whether a bid was withdrawn would be disclosed after the close of every round, but the identities of bidders placing specific bids or withdrawals and the net bid amounts would not be disclosed until after the close of the auction.

10. Bidders would have access to additional information about their own bids. For example, bidders would be able to view their own level of eligibility, before and during the auction, through the Commission's Integrated Spectrum Auction System (FCC Auction System).

11. For purposes of complying with 47 CFR 1.2105(c), the Commission's rule prohibiting certain communications between applicants (formerly referred to as the anti-collusion rule), applicants would be made aware of other applicants with which they will not be permitted to cooperate, collaborate, or communicate—including discussing bids, bidding strategies, or post-auction market structure. Specifically, the Bureau would notify separately each applicant in Auction 92 whether applicants with short-form applications to participate in pending auctions, including but not limited to Auction 92, have applied for licenses in any of the same or overlapping geographic areas as that applicant.

12. After the close of bidding, bidders' license selections, upfront payment amounts, bidding eligibility, bids, and other bidding-related actions would be made publicly available.

13. The Bureau seeks comment on its proposal to implement anonymous bidding in Auction 92. The Bureau also seeks comment on alternatives to the use of anonymous bidding procedures for Auction 92. When the Commission proposed limited information disclosure procedures in 2006, it did so in response to analysis suggesting that under certain circumstances the competitiveness and economic efficiency of a simultaneous multiple-round auction may be enhanced if such information is withheld until after the close of the auction. The Bureau encourages parties to provide information about the benefits and costs of complying with limited information procedures as compared with the benefits and costs of alternative procedures that would provide for the disclosure of more information on bidder identities and interests in the auction. If commenters believe that the Bureau should not adopt procedures to limit the disclosure of certain bidder-specific information until after the auction, they should explain their reasoning.

iii. Bidding Rounds

14. Auction 92 will consist of sequential bidding rounds. The initial bidding schedule will be announced in a public notice to be released at least one week before the start of the auction.

15. The Commission will conduct Auction 92 over the Internet, and telephonic bidding will be available as well. The toll-free telephone number for the Auction Bidder Line will be provided to qualified bidders.

16. The Bureau proposes to retain the discretion to change the bidding schedule in order to foster an auction pace that reasonably balances speed with the bidders' need to study round results and adjust their bidding strategies. Under this proposal, the Bureau may change the amount of time for bidding rounds, the amount of time between rounds, or the number of rounds per day, depending upon bidding activity and other factors. The Bureau seeks comment on this proposal. Commenters may wish to address the role of the bidding schedule in managing the pace of the auction, specifically discussing the tradeoffs in managing auction pace by bidding schedule changes, by changing the activity requirements or bid amount parameters, or by using other means.

iv. Stopping Rule

17. The Bureau has discretion to establish stopping rules before or during a multiple round auction in order to end the auction within a reasonable time. For Auction 92, the Bureau proposes to employ a simultaneous stopping rule approach. A simultaneous stopping rule means that all licenses remain available for bidding until bidding closes simultaneously on all licenses. More specifically, bidding will close simultaneously on all licenses after the first round in which no bidder submits any new bid, applies a proactive waiver, or withdraws any provisionally winning bid, a bid that would become a final winning bid if the auction were to close in that given round. Thus, unless the Bureau announces alternative stopping procedures, bidding will remain open on all licenses until bidding stops on every license. It is not possible to determine in advance how long the auction will last.

18. Further, the Bureau proposes to retain the discretion to exercise any of the following options during Auction 92. (A) Use a modified version of the simultaneous stopping rule that would close the auction for all licenses after the first round in which no bidder applies a waiver, withdraws a provisionally winning bid, or places any new bids on any license for which it is not the provisionally winning bidder. Thus, absent any other bidding activity, a bidder placing a new bid on a license for which it is the provisionally winning bidder would not keep the auction open under this modified stopping rule. (B) Use a modified version of the simultaneous stopping rule that would close the auction for all licenses after the first round in which no bidder applies a waiver, withdraws a provisionally winning bid, or places any new bids on any license that is not FCC held. Thus, absent any other bidding activity, a bidder placing a new bid on an FCC-held license (a license that does not already have a provisionally winning bid) would not keep the auction open under this modified stopping rule. (C) Use a modified version of the simultaneous stopping rule that combines (A) and (B). (D) Declare that the auction will end after a specified number of additional rounds (special stopping rule). If the Bureau invokes this special stopping rule, it will accept bids in the specified final round(s) after which the auction will close. (E) Keep the auction open even if no bidder submits any new bids, applies a waiver, or withdraws any provisionally winning bids. In this event, the effect will be the same as if a bidder had applied a waiver. The activity rule, therefore, will apply as usual and a bidder with insufficient activity will either use a waiver or lose bidding eligibility.

19. The Bureau proposes to exercise these options only in certain circumstances, for example, where the auction is proceeding unusually slowly

or quickly, there is minimal overall bidding activity, or it appears likely that the auction will not close within a reasonable period of time or will close prematurely. Before exercising certain of these options, the Bureau is likely to attempt to change the pace of the auction by, for example, changing the number of bidding rounds per day and/or changing minimum acceptable bids. The Bureau proposes to retain the discretion to exercise any of these options with or without prior announcement during the auction. The Bureau seeks comment on these proposals.

v. Information Relating to Auction Delay, Suspension, or Cancellation

20. For Auction 92, the Bureau proposes that, by public notice or by announcement during the auction, the Bureau may delay, suspend, or cancel the auction in the event of natural disaster, technical obstacle, administrative or weather necessity, evidence of an auction security breach or unlawful bidding activity, or for any other reason that affects the fair and efficient conduct of competitive bidding. In such cases, the Bureau, in its sole discretion, may elect to resume the auction starting from the beginning of the current round, resume the auction starting from some previous round, or cancel the auction in its entirety. Network interruption may cause the Bureau to delay or suspend the auction. The Bureau emphasizes that exercise of this authority is solely within the discretion of the Bureau, and its use is not intended to be a substitute for situations in which bidders may wish to apply their activity rule waivers. The Bureau seeks comment on this proposal.

B. Auction Procedures

i. Upfront Payments and Bidding Eligibility

21. The Bureau has delegated authority and discretion to determine an appropriate upfront payment for each license being auctioned, taking into account such factors as the efficiency of the auction process and the potential value of similar licenses. The upfront payment is a refundable deposit made by each bidder to establish eligibility to bid on licenses. Upfront payments that are related to the specific licenses being auctioned protect against frivolous or insincere bidding and provide the Commission with a source of funds from which to collect payments owed at the close of the auction. With these considerations in mind, the Bureau proposes the upfront payments set forth in Attachment A to the *Auction 92 Comment Public Notice.* The Bureau seeks comment on this proposal.

22. The Bureau further proposes that the amount of the upfront payment submitted by a bidder will determine the bidder's initial bidding eligibility in bidding units. The Bureau proposes that each license be assigned a specific number of bidding units equal to one bidding unit per dollar of the upfront payment listed in Attachment A of the *Auction 92 Comment Public Notice.* The number of bidding units for a given license is fixed and does not change during the auction as prices change. A bidder may place bids on multiple licenses, provided that the total number of bidding units associated with those licenses does not exceed the bidder's current eligibility. Eligibility cannot be increased during the auction; it can only remain the same or decrease. Thus, in calculating its upfront payment amount and hence its initial bidding eligibility, an applicant must determine the maximum number of bidding units it may wish to bid on (or hold provisionally winning bids) in any single round, and submit an upfront payment amount covering that total number of bidding units. The Bureau seeks comment on these proposals.

ii. Activity Rule

23. In order to ensure that the auction closes within a reasonable period of time, an activity rule requires bidders to bid actively throughout the auction, rather than wait until late in the auction before participating. A bidder's activity in a round will be the sum of the bidding units associated with any licenses upon which it places bids during the current round and the bidding units associated with any licenses for which it holds provisionally winning bids placed in previous rounds. Bidders are required to be active on a specific percentage of their current bidding eligibility during each round of the auction. Failure to maintain the requisite activity level will result in the use of an activity rule waiver, if any remain, or a reduction in the bidder's eligibility, possibly curtailing or eliminating the bidder's ability to place additional bids in the auction.

24. The Bureau proposes to divide the auction into at least two stages, each characterized by a different activity requirement. The auction will start in Stage One. The Bureau proposes to advance the auction to the next stage by announcement during the auction. In exercising this discretion, the Bureau will consider a variety of measures of auction activity, including but not limited to the percentage of licenses (as measured in bidding units) on which there are new bids, the number of new bids, and the increase in revenue. The Bureau seeks comment on these proposals.

25. While noting that the Bureau retains the discretion to change stages unilaterally by announcement during the auction, the Bureau proposes in each round of the first stage of the auction that a bidder desiring to maintain its current bidding eligibility would be required to be active on licenses representing at least 80 percent of its current bidding eligibility. Failure to maintain the required activity level will result in the use of an activity rule waiver or a reduction in the bidder's bidding eligibility for the next round of bidding. During Stage One, a bidder's reduced eligibility for the next round will be calculated by multiplying the bidder's current round activity by five-fourths (5/4). The Bureau proposes further that in each round of the second stage of the auction a bidder desiring to maintain its current bidding eligibility is required to be active on 95 percent of its current bidding eligibility. Failure to maintain the required activity level will result in the use of an activity rule waiver or a reduction in the bidder's bidding eligibility for the next round of bidding. During Stage Two, a bidder's reduced eligibility for the next round will be calculated by multiplying the bidder's current round activity by twenty-nineteenths (20/19).

26. The Bureau requests comment on these activity requirements. Under this proposal, the Bureau will retain the discretion to change the activity requirements during the auction. For example, the Bureau could decide to add an additional stage with a higher activity requirement, not to transition to Stage Two if it believes the auction is progressing satisfactorily under the Stage One activity requirement, or to transition to Stage Two with an activity requirement that is higher or lower than the 95 percent proposed herein. If the Bureau exercises this discretion, it will alert bidders by announcement in the FCC Auction System. Moreover, if the Bureau implements stages with activity requirements other than the ones listed above, a bidder's reduced eligibility for the next round will be calculated by multiplying the bidder's current round activity by the reciprocal of the activity requirement. For example, with a 98 percent activity requirement, the bidder's current round activity would be multiplied by 50/49; with a 100 percent activity requirement, the bidder's current round activity would become its bidding eligibility (current round activity would be multiplied by 1/1).

iii. Activity Rule Waivers and Reducing Eligibility

27. Use of an activity rule waiver preserves the bidder's eligibility despite the bidder's activity in the current round being below the required minimum level. An activity rule waiver applies to an entire round of bidding, not to a particular license. Activity rule waivers can be either proactive or automatic and are principally a mechanism for an auction participant to avoid the loss of bidding eligibility in the event that exigent circumstances prevent the participant from bidding in a particular round.

28. The FCC Auction System assumes that a bidder that does not meet the activity requirement would prefer to use an activity rule waiver (if available) rather than lose bidding eligibility. Therefore, the system will automatically apply a waiver at the end of any bidding round in which a bidder's activity level is below the minimum required unless: (1) The bidder has no activity rule waivers remaining; or (2) the bidder overrides the automatic application of a waiver by reducing eligibility, thereby meeting the activity requirement. If a bidder has no waivers remaining and does not satisfy the required activity level, its current eligibility will be permanently reduced, possibly curtailing or eliminating the bidder's ability to place additional bids in the auction.

29. A bidder with insufficient activity may wish to reduce its bidding eligibility rather than use an activity rule waiver. If so, the bidder must affirmatively override the automatic waiver mechanism during the bidding round by using the reduce eligibility function in the FCC Auction System. In this case, the bidder's eligibility is permanently reduced to bring the bidder into compliance with the activity rule. Reducing eligibility is an irreversible action; once eligibility has been reduced, a bidder will not be permitted to regain its lost bidding eligibility, even if the round has not yet closed.

30. Under the proposed simultaneous stopping rule, a bidder may apply an activity rule waiver proactively as a means to keep the auction open without placing a bid. If a bidder proactively applies an activity rule waiver (using the apply waiver function in the FCC Auction System) during a bidding round in which no bids are placed or withdrawn, the auction will remain open and the bidder's eligibility will be preserved. An automatic waiver applied by the FCC Auction System in a round in which there are no new bids, withdrawals, or proactive waivers will not keep the auction open. A bidder cannot apply a proactive waiver after bidding in a round, and applying a proactive waiver will preclude a bidder from placing any bids in that round. In fact, once a bidder places a proactive waiver during a round, the FCC Auction System does not allow the bidder to take other bidding-related action in that round, including placing or withdrawing bids. Applying a waiver is irreversible; once a proactive waiver is submitted, that waiver cannot be unsubmitted, even if the round has not yet closed.

31. Consistent with recent auctions of wireless spectrum, the Bureau proposes that each bidder in Auction 92 be provided with three activity rule waivers that may be used at the bidder's discretion during the course of the auction. The Bureau seeks comment on this proposal.

iv. Reserve Price or Minimum Opening Bids

32. Consistent with the mandate of 47 U.S.C. 309(j), the Bureau seeks comment on the use of a minimum opening bid amount and/or reserve price for this auction.

33. Normally, a reserve price is an absolute minimum price below which an item will not be sold in a given auction. Reserve prices can be either published or unpublished. A minimum opening bid, on the other hand, is the minimum bid price set at the beginning of the auction below which no bids are accepted. It is generally used to accelerate the competitive bidding process. It is possible for the minimum opening bid and the reserve price to be the same amount.

34. The Bureau proposes to establish minimum opening bid amounts for Auction 92 as an effective bidding tool for accelerating the competitive bidding process. The Bureau does not propose to establish a separate reserve price for the licenses to be offered in Auction 92.

35. For Auction 92, the Bureau proposes to calculate minimum opening bid amounts on a license-by-license basis using a method that takes into consideration the amounts bid for the same licenses in Auction 73, when these licenses received multiple bids. Specifically, for each license the Bureau proposes to calculate the minimum opening bid amount as the greater of (1) the minimum opening bid amount for the same license in Auction 73, or (2) 10% of the highest bid amount received for the license in Auction 73. This approach makes it possible to establish somewhat higher minimum opening bids for licenses that may likely sell for relatively higher prices, thereby potentially reducing the number of bidding rounds necessary for licenses to reach their final auction prices. The proposed minimum opening bid amount for each license is available in Attachment A of the *Auction 92 Comment Public Notice.* The Bureau seeks comment on this proposal.

36. If commenters believe that these minimum opening bid amounts will result in unsold licenses, are not reasonable amounts, or should instead operate as reserve prices, they should explain why this is so, and comment on the desirability of an alternative approach. If requesting a lower minimum opening bid amount for a specific license offered in this auction, a commenter should justify the requested amount in detail. Commenters are advised to support their claims with valuation analyses and suggested amounts or formulas for reserve prices or minimum opening bids. In establishing minimum opening bid amounts, the Bureau particularly seeks comment on factors that could reasonably have an impact on valuation of the spectrum being auctioned, including levels of incumbency within these spectrum bands, the availability of technology to provide service, the size of the geographic service areas, issues of interference with other spectrum bands, and any other relevant factors. The Bureau seeks comment on this approach, and on whether, consistent with 47 U.S.C. 309(j), the public interest would be served by having no minimum opening bid amount or reserve price.

v. Bid Amounts

37. The Bureau proposes that, in each round, eligible bidders be able to place a bid on a given license using one or more pre-defined bid amounts (provided the bidder has sufficient eligibility to place a bid on the particular license). Under this proposal, the FCC Auction System interface will list the acceptable bid amounts for each license.

vi. Minimum Acceptable Bids

38. The first of the bid amounts is called the minimum acceptable bid amount. The minimum acceptable bid amount for a license will be equal to its minimum opening bid amount until there is a provisionally winning bid on the license. After there is a provisionally winning bid for a license, the minimum acceptable bid amount for that license will be equal to the amount of the provisionally winning bid plus a percentage of that bid amount calculated by the Bureau using a specified formula. In general, the percentage will be higher for a license

receiving many bids than for a license receiving few bids. In the case of a license for which the provisionally winning bid has been withdrawn, the minimum acceptable bid amount will equal the second highest bid received for the license.

39. The percentage of the provisionally winning bid used to establish the minimum acceptable bid amount (the additional percentage) is calculated at the end of each round, based on an activity index. The activity index is a weighted average of (a) the number of bidders placing a bid on the license, and (b) the activity index from the prior round. Specifically, the activity index is equal to a weighting factor times the number of bidders placing a bid covering the license in the most recent bidding round plus one minus the weighting factor times the activity index from the prior round, except for Round 1 calculations, when the activity index is set at 0 because there is no prior round. The additional percentage is determined as one plus the activity index times a minimum percentage amount, with the result not to exceed a given maximum percentage. The additional percentage is then multiplied by the provisionally winning bid amount, with the results rounded using the Commission's standard procedure for auctions, to obtain the minimum acceptable bid for the next round. The Bureau proposes initially to set the weighting factor at 0.5, the minimum percentage at 0.1 (10%), and the maximum percentage at 0.3 (30%). Hence, at these initial settings, the minimum acceptable bid for a license will be between ten percent and thirty percent higher than the provisionally winning bid, depending upon the bidding activity for the license. Equations and examples of calculations are shown in Attachment B of the *Auction 92 Comment Public Notice.*

vii. Additional Bid Amounts

40. The Bureau proposes to calculate any additional bid amounts using the minimum acceptable bid amount and a bid increment percentage—more specifically, by multiplying the minimum acceptable bid by one plus successively higher multiples of the bid increment percentage. If, for example, the bid increment percentage is 5 percent, the calculation of the first additional acceptable bid amount is (minimum acceptable bid amount) * (1 + 0.05), or (minimum acceptable bid amount) * 1.05; the second additional acceptable bid amount equals the minimum acceptable bid amount times one plus two times the bid increment percentage, or (minimum acceptable bid amount) * 1.1, etc. The Bureau proposes to use a bid increment percentage of 5 percent.

41. The Bureau proposes to start with eight additional bid amounts (for a total of nine bid amounts), and seeks comment on whether to use fewer or no additional bid amounts. In particular, commenters should address the issue of additional bid amounts in light of particular circumstances of Auction 92, including the nature of the licenses offered.

viii. Bid Amount Changes

42. The Bureau retains the discretion to change the minimum acceptable bid amounts, the additional bid amounts, the number of acceptable bid amounts, and the parameters of the formulas used to calculate minimum acceptable bid amounts and additional bid amounts if the Bureau determines that circumstances so dictate. Further, the Bureau retains the discretion to make such changes on a license-by-license basis.

43. The Bureau also retains the discretion to limit (a) the amount by which a minimum acceptable bid for a license may increase compared with the corresponding provisionally winning bid, and (b) the amount by which an additional bid amount may increase compared with the immediately preceding acceptable bid amount. For example, the Bureau could set a $1 million limit on increases in minimum acceptable bid amounts over provisionally winning bids. Thus, if the activity-based formula calculates a minimum acceptable bid amount that is $2 million higher than the provisionally winning bid on a license, the minimum acceptable bid amount would instead be capped at $1 million above the provisionally winning bid. The Bureau seeks comment on the circumstances under which the Bureau should employ such a limit, factors it should consider when determining the dollar amount of the limit, and the tradeoffs in setting such a limit or changing parameters of the activity-based formula, such as changing the minimum percentage. If the Bureau exercises this discretion, it will alert bidders by announcement in the FCC Auction System.

44. The Bureau seeks comment on its bid amount proposals. Commenters may wish to address the role of the minimum acceptable bids and the number of acceptable bid amounts in managing the pace of the auction and the tradeoffs in managing auction pace by changing the bidding schedule, activity requirements, or bid amounts, or by using other means.

ix. Provisionally Winning Bids

45. Provisionally winning bids are bids that would become final winning bids if the auction were to close in that given round. At the end of a bidding round, a provisionally winning bid for each license will be determined based on the highest bid amount received for the license. In the event of identical high bid amounts being submitted on a license in a given round (i.e., tied bids), the Bureau will use a random number generator to select a single provisionally winning bid from among the tied bids. (Each bid is assigned a random number, and the tied bid with the highest random number wins the tiebreaker.) The remaining bidders, as well as the provisionally winning bidder, can submit higher bids in subsequent rounds. However, if the auction were to end with no other bids being placed, the winning bidder would be the one that placed the provisionally winning bid. If any bids are received on the license in a subsequent round, the provisionally winning bid again will be determined by the highest bid amount received for the license.

46. A provisionally winning bid will remain the provisionally winning bid until there is a higher bid on the license at the close of a subsequent round, unless the provisionally winning bid is withdrawn. Bidders are reminded that provisionally winning bids count toward activity for purposes of the activity rule.

x. Bid Removal

47. For Auction 92, the Bureau proposes and seeks comment on the following bid removal procedures. Before the close of a bidding round, a bidder has the option of removing any bid placed in that round. By removing selected bids in the FCC Auction System, a bidder may effectively undo any of its bids placed within that round. In contrast to a bid withdrawal, a bidder removing a bid placed in the same round is not subject to a withdrawal payment. Once a round closes, a bidder may no longer remove a bid.

xi. Bid Withdrawal

48. The Bureau also seeks comment on the following bid withdrawal procedures. When permitted in an auction, bid withdrawals provide a bidder with the option of withdrawing bids placed in prior rounds that have become provisionally winning bids. A bidder may withdraw its provisionally winning bids using the withdraw bids function in the FCC Auction System. A bidder that withdraws its provisionally winning bid(s) is subject to the bid

withdrawal payment provisions of 47 CFR 1.2104(g) and 1.2109.

49. For Auction 92, the Bureau proposes to limit each bidder to withdrawing provisionally winning bids in only one round during the course of the auction. To permit a bidder to withdraw bids in more than one round may encourage insincere bidding or the use of withdrawals for anti-competitive purposes. The round in which withdrawals may be used will be at the bidder's discretion, and there is no limit on the number of provisionally winning bids that may be withdrawn during that round. Withdrawals must be in accordance with the Commission's rules, including the bid withdrawal payment provisions specified in 47 CFR 1.2104(g). The withdrawal payment amount is deducted from any upfront payments or down payments that the withdrawing bidder has deposited with the Commission.

50. The Bureau seeks comment on these bid withdrawal procedures. If commenters believe that each bidder should be allowed to withdraw provisionally winning bids in more than one round during the course of the auction, they should state how many bid withdrawal rounds they seek and explain what specific factors lead them to that conclusion. If commenters believe that bidders in this auction should not be permitted to withdraw any bids, they should discuss their reasoning for this suggestion.

C. Post-Auction Payments

i. Interim Withdrawal Payment Percentage

51. The Bureau seeks comment on the appropriate percentage of a withdrawn bid that should be assessed as an interim withdrawal payment in the event that a final withdrawal payment cannot be determined at the close of the auction. In general, 47 CFR 1.2104(g) provides that a bidder that withdraws a bid during an auction is subject to a withdrawal payment equal to the difference between the amount of the withdrawn bid and the amount of the winning bid in the same or subsequent auction(s). If a bid is withdrawn and no subsequent higher bid is placed and/or the license is not won in the same auction, the final withdrawal payment cannot be calculated until after the close of a subsequent auction in which a higher bid for the license (or the equivalent to the license) is placed or the license is won. When that final payment cannot yet be calculated, the bidder responsible for the withdrawn bid is assessed an interim bid withdrawal payment, which will be applied toward any final bid withdrawal payment that is ultimately assessed. 47 CFR 1.2104(g)(1) requires that the percentage of the withdrawn bid to be assessed as an interim bid withdrawal payment be between 3 percent and 20 percent and that it be set in advance of the auction.

52. The Commission has determined that the level of the interim withdrawal payment in a particular auction will be based on the nature of the service and the inventory of the licenses being offered. The Commission has noted that it may impose a higher interim withdrawal payment percentage to deter the anti-competitive use of withdrawals when, for example, bidders likely will not need to aggregate the licenses being offered in the auction, such as when few licenses are offered that are on adjacent frequencies or in adjacent areas, or when there are few synergies to be captured by combining licenses.

53. With respect to the licenses being offered in Auction 92, the opportunities for combining in this auction licenses on adjacent frequencies or in adjacent areas may be limited, so there is likely to be little need to use withdrawals to protect against incomplete aggregations. Therefore, the Bureau proposes to establish the percentage of the withdrawn bid to be assessed as an interim bid withdrawal payment at 15 percent for this auction. The Bureau seeks comment on this proposal.

ii. Additional Default Payment Percentage

54. Any winning bidder that defaults or is disqualified after the close of an auction (i.e., fails to remit the required down payment within the prescribed period of time, fails to submit a timely long-form application, fails to make full payment, or is otherwise disqualified) is liable for a default payment under 47 CFR 1.2104(g)(2). This payment consists of a deficiency payment, equal to the difference between the amount of the bidder's bid and the amount of the winning bid the next time a license covering the same spectrum is won in an auction, plus an additional payment equal to a percentage of the defaulter's bid or of the subsequent winning bid, whichever is less.

55. The Commission's rules provide that, in advance of each auction, a percentage shall be established for the additional default payment. This percentage must be between 3 percent and 20 percent of the applicable bid. As the Commission has indicated, the level of this additional payment in each auction will be based on the nature of the service and the inventory of the licenses being offered.

56. For Auction 92, the Bureau proposes to establish an additional default payment of 15 percent. Given the nature of the service and the inventory of the licenses being offered in Auction 92, the Bureau believes that an additional default payment of 15 percent of the relevant bid will provide a sufficient deterrent to defaults. The Bureau seeks comment on this proposal.

IV. Ex Parte Procedures

57. This proceeding has been designated as a permit-but-disclose proceeding in accordance with the Commission's *ex parte* rules. Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentations must contain summaries of the substance of the presentations and not merely a listing of the subjects discussed. More than a one or two sentence description of the views and arguments presented is generally required. Other

rules pertaining to oral and written *ex parte* presentations in permit-but-disclose proceedings are set forth in 47 CFR 1.1206(b).

William W. Huber,

Associate Chief, Auctions and Spectrum Access Division, WTB, Federal Communications Commission.

[FR Doc. 2011–122 Filed 1–6–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS11–01]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in open session for its regular meeting:

Location: FDIC—L. William Seidman Center, 3501 Fairfax Drive, Room B3124 Arlington, VA 22226.

Date: January 12, 2011.

Time: 10:30 a.m.

Status: Open.

Matters To Be Considered

Summary Agenda

December 8, 2010 minutes—Open Session. (No substantive discussion of

the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

Discussion Agenda

- Appraisal Foundation September 2010 Grant Reimbursement Request;
- 2011 Appraisal Foundation Grant Request;
- Determination as to whether an Appraisal Complaint National Hotline Exists: Pursuant to Section 1473(p) of the Dodd-Frank Wall Street Reform and Consumer Protection Act; and
- Oregon Compliance Review.

How To Attend and Observe an ASC Meeting

E-mail your name, organization and contact information *meetings@asc.gov.* You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street, NW., Ste 760, Washington, DC 20005. Your request must be received no later than 4:30 p.m., ET, on the Monday prior to the meeting. If that Monday is a Federal holiday, then your request must be received 4:30 p.m., ET on the previous Friday. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis.

Dated: January 4, 2011.

James R. Park,

Executive Director.

[FR Doc. 2011–103 Filed 1–6–11; 8:45 am]

BILLING CODE P

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

[Docket No. AS11–02]

Appraisal Subcommittee Notice of Meeting

AGENCY: Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

ACTION: Notice of meeting.

Description: In accordance with Section 1104(b) of Title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, as amended, notice is hereby given that the Appraisal Subcommittee (ASC) will meet in closed session:

Location: FDIC—L. William Seidman Center, 3501 Fairfax Drive, Room B3124, Arlington, VA 22226.

Date: January 12, 2011.

Time: Immediately following the ASC open session beginning at 11:15 a.m.

Status: Closed.

Matters To Be Considered: December 8, 2010 minutes—Closed Session. Preliminary discussion of State Compliance Reviews.

Dated: January 4, 2011.

James R. Park,

Executive Director.

[FR Doc. 2011–105 Filed 1–6–11; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 21, 2011.

A. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. *Mehrdad Elie,* Redwood City, California; to acquire voting securities of HarVest BanCorp, Gaithersburg, Maryland, and thereby indirectly acquire voting shares of HarVest Bank of Maryland, Rockville, Maryland.

B. Federal Reserve Bank of Minneapolis (Jacqueline G. King, Community Affairs Officer) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Russell James Gesell,* individually and as co-trustee of The Charles R. Gesell Irrevocable Trust, and The Peter J. Gesell Irrevocable Trust, all in Saint Paul, Minnesota; and Russell James Gesell, Rene J. Gesell, The Charles R. Gesell Irrevocable Trust and The Peter J. Gesell Irrevocable Trust as part of The Gesell Family Group; to retain voting shares of Cherokee Bancshares, Inc., and thereby indirectly retain control of BankCherokee, both in Saint Paul, Minnesota.

Board of Governors of the Federal Reserve System, January 3, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–70 Filed 1–6–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 31, 2011.

A. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *First National Bancorp, Inc.,* Green Forest, Arkansas; to acquire up to 8.11 percent of the voting shares of Legacy National Bank, Springdale, Arkansas.

Board of Governors of the Federal Reserve System, January 3, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–69 Filed 1–6–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 3, 2011.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Choice Bancorp, Inc.,* Oshkosh, Wisconsin; to become a bank holding company by acquiring 100 percent of the voting shares of Choice Bank, Oshkosh, Wisconsin.

Board of Governors of the Federal Reserve System, January 4, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–102 Filed 1–6–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: CMS–10339]

Office of Consumer Information and Insurance Oversight; Emergency Clearance; Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Office of Consumer Information and Insurance Oversight, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of Consumer Information and Insurance Oversight (OCIIO), the U.S. Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information requested below. In compliance with the requirement of Section 3506(c)(2)(a) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. In accordance with 5 CFR 1320.13, we are requesting an emergency review to ensure compliance with an initiative of the Administration.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Pre-Existing Health Insurance Plan and Supporting Regulations; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148. Section 1101 of the law establishes a "temporary high risk health insurance pool program" (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with States or private, non-profit entities.

We are requesting a revision for this package because this information is needed to assure that PCIP programs are established timely and effectively. HHS is now seeking emergency approval for this collection. The collection has been revised to include the burden associated with portability requirements. This request is being made based on regulations and guidance that have been issued and contracts which have been executed by HHS with States or an entity on their behalf participating in the PCIP program. PCIP is also referred to as the temporary qualified high risk insurance pool program, as it is called in the Affordable Care Act, but we have adopted the term PCIP to better describe the program and avoid confusion with the existing State high risk pool programs. Form Number: CMS–10339 (OMB#: 0938–1100); Frequency: Reporting—On occasion; Affected Public: State governments; Number of Respondents: 51; Total Annual Responses: 2,652; Total Annual Hours: 36,924. (For policy questions regarding this collection contact Laura Dash at 410–786–8623. For all other issues call 410–786–1326.)

OCIIO is requesting OMB approval by *January 18, 2011,* with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by *January 18, 2011.*

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections references above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995* or E-mail your request, including your address, phone number, OMB Number, and CMS document identifier to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested parties are invited to send comments regarding the burden or any other aspect of these collections of information requirements. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *January 18, 2011:*

1. *Electronically.* You may submit your comments electronically to *http://Regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: Paperwork Reduction Act, Room 445–G, Hubert H.

Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

3. *By facsimile or E-mail to OMB.* OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number (202) 395–6974, E-mail: *OIRA_submission@omb.eop.gov.*

Dated: January 4, 2011.

Kenneth Cohen,

Director, Executive Secretariat & Regulatory Affairs, Office of Consumer Information and Insurance Oversight.

[FR Doc. 2011–142 Filed 1–6–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service (DHHS) is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will be held Thursday, January 27, 2011 and Friday, January 28, 2011. The meeting will be held from 10 a.m. to approximately 5 p.m. on January 27, 2011 and 9 a.m. to approximately 3 p.m. on January 28, 2011.

ADDRESSES: Department of Health and Human Services, Room 800, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Mr. Melvin Joppy, Committee Manager, Presidential Advisory Council on HIV/AIDS, Department of Health and Human Services, 200 Independence Avenue, Room 443H, Hubert H. Humphrey Building, Washington, DC 20201; (202) 690–5560. More detailed information about PACHA can be obtained by accessing the Council's Web site at *http://www.pacha.gov.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995 as amended by Executive Order 13009, dated June 14, 1996. The Council provides advice, information, and recommendations to the Secretary regarding programs and policies to promote effective prevention and cure of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. The agenda and draft resolutions for the upcoming meeting will be posted on the Council's Web site *http://www.pacha.gov.*

Public attendance at the meeting is limited to space available. Individuals must provide a photo ID for entry into the building. Individuals who plan to attend and need special assistance, such as language interpretation or reasonable accommodations, should notify the designated contact person. Pre-registration for public attendance is advisable and can be accomplished by contacting the PACHA Committee Manager.

Members of the public will have the opportunity to provide comments on January 28, 2011. Pre-registration is required for public comment. Any individual who wishes to participate in the public comment session must contact: Melvin Joppy, Office of HIV/AIDS Policy, *melvin.joppy@hhs.gov,* by close of business Monday, January 24, 2011. Public comment will be limited to three minutes per speaker. Members of the public who wish to have printed materials distributed to PACHA members for discussion at the meeting are asked to provide, at a minimum, 30 copies of the materials to the PACHA Committee Manager no later than close of business Monday, January 24, 2011. Contact information for the PACHA Committee Manager is provided above.

Dated: December 28, 2010.

Christopher H. Bates,

Executive Director, Presidential Advisory on HIV/AIDS.

[FR Doc. 2011–119 Filed 1–6–11; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 75 FR 70276–70277, dated November 17, 2010) is amended to reflect the title change for the Office of Science Quality and Translation, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title for the Office of Science Quality and Translation (CASH) and insert the Office of Science Quality (CASH).

Dated: December 29, 2010.

Barbara Harris,

Acting Chief Operating Officer, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2011–55 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10339]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden

estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Pre-Existing Health Insurance Plan and Supporting Regulations; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148. Section 1101 of the law establishes a "temporary high risk health insurance pool program" (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with states or private, non-profit entities.

We are requesting an extension of this package because this information is needed to assure that PCIP programs are established timely and effectively. This request is being made based on regulations and guidance that have been issued and contracts which have been executed by HHS with States or an entity on their behalf participating in the PCIP program. PCIP is also referred to as the temporary qualified high risk insurance pool program, as it is called in the Affordable Care Act, but we have adopted the term PCIP to better describe the program and avoid confusion with the existing state high risk pool programs. *Form Number:* CMS–10339 (OMB#: 0938–1100); Frequency: Reporting—On occasion; *Affected Public:* State governments; Number of Respondents: 51; Total Annual Responses: 2,652; *Total Annual Hours:* 36,924. (For policy questions regarding this collection contact Laura Dash at 410–786–8623. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by: March 8, 2011.

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 4, 2011.

Kenneth Cohen,

Director, Executive Secretariat & Regulatory Affairs, Office of Consumer Information and Insurance Oversight.

[FR Doc. 2011–140 Filed 1–6–11; 8:45 am]

BILLING CODE 4120–01–U–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0001]

Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's Health and Diet Survey.

DATES: Submit either electronic or written comments on the collection of information by March 8, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Health and Diet Survey (OMB Control Number 0910–0545—Extension)

FDA is seeking extension of OMB approval for the Health and Diet Survey, which is a voluntary consumer survey

intended to gauge and track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition and physical activity. The authority for FDA to collect the information derives from FDA's Commissioner of Food and Drugs authority provided in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The survey consists of two independent data collection activities. One collection, entitled "Health and Diet Survey—General Topics," tracks a broad range of consumer attitudes, awareness, knowledge, and self-reported behaviors related to key diet and health issues. The other collection, entitled "Health and Diet Survey—*Dietary Guidelines* Supplement," will provide FDA with updated information about consumer attitudes, awareness, knowledge, and behavior regarding various elements of nutrition and physical activity based on the key recommendations of the *Dietary Guidelines for Americans,* which are jointly issued by the Department of Health and Human Services and the U.S. Department of Agriculture every 5 years.

The information to be collected with the Health and Diet Survey—General Topics will include: (1) Awareness of diet-disease relationships, (2) food and dietary supplement label use, (3) dietary practices including strategies to lose or maintain weight, and (4) awareness and knowledge of dietary fats. This survey has been repeated approximately every 3 years over the course of the past several years for the purpose of tracking changes and trends in public opinions and consumer behavior, with some new questions added or omitted or partially modified each iteration in response to current events. In the next 3 years, FDA plans to field the Health and Diet Survey—General Topics in 2012 and anticipates that it might have the need for additional iterations in 2014. The information to be collected with the Health and Diet Survey—*Dietary Guidelines* Supplement will include: (1) Awareness and sources of information, (2) attitudes toward diet and physical activity, and (3) practice and knowledge related to recommended behaviors. The survey will also ask about perceptions and use of Federal nutrition information, special diet, weight status, health status, and demographics. In the next 3 years, FDA anticipates to field the Health and Diet Survey—*Dietary Guidelines* Supplement in 2011–2012.

FDA and other Federal Agencies will use the information from the Health and Diet Survey to evaluate and develop strategies and programs to encourage and help consumers adopt healthy lifestyles. The information will also help FDA and other Federal Agencies evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health.

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 States and the District of Columbia. Participation will be voluntary.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
General Topics: Pretest	27	1	27	0.25	7
General Topics: Screener	10,000	1	10,000	0.02	200
General Topics: Survey	3,000	1	3,000	0.25	750
Dietary Guidelines Supplement: Screener	4,000	1	4,000	0.02	80
Dietary Guidelines Supplement: Survey	1,200	1	1,200	0.22	264
Total					1,301

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate of the number of respondents and the hours per response on its experience with previous Health and Diet Surveys. Prior to the administration of the Health and Diet Survey—General Topics, the Agency plans to conduct a pretest to identify and resolve potential problems. The pretest will be conducted with 27 participants; we estimate that it will take a respondent 15 minutes (0.25 hours) to complete the pretest, for a total of 6.75 hours, rounded to 7. The Agency will use a screener to select an eligible adult respondent in each household to participate in the survey. For the Health and Diet Survey—General Topics data collection activity, a total of 10,000 individuals in the 50 States and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening, for a total of 200 hours. We estimate that 3,000 eligible adults will participate in the survey, each taking 15 minutes (0.25 hours), for a total of 750 hours. For the Health and Diet Survey—Dietary Guidelines Supplement data collection activity, 4,000 individuals in the 50 States and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions, for a total of 80 hours. Of these respondents, 1,200 will complete the survey. We estimate that it will take a respondent 13 minutes (0.22 hours) to complete the entire survey, for a total of 264 hours. Thus, the total estimated burden is 1,301 hours.

Dated: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–85 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0492]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices: Recommended Glossary and Educational Outreach To Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 7, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0553. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, e-mail: *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use—(OMB Control Number 0910–0553)—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.

In the **Federal Register** of November 30, 2004 (69 FR 69606), FDA published a notice of availability of the guidance entitled "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use." The guidance document provides guidance for the voluntary use of selected symbols in place of text in labeling. It provides the labeling guidance required for: (1) In vitro diagnostic devices (IVDs), intended for professional use under 21 CFR 809.10, FDA's labeling requirements for IVDs; and (2) FDA's labeling requirements for biologics, including IVDs under 21 CFR parts 610 and 660. Under section 502(c) of the FD&C Act, a drug or device is misbranded, "* * *If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

The guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. Furthermore, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and educational outreach information will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the FD&C Act and section 351 of the PHS Act.

The likely respondents for this collection of information are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

The glossary activity is inclusive of both domestic and foreign IVD manufacturers. FDA receives submissions from approximately 689 IVD manufacturers annually. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary for the specific symbols used in labels or labeling for the IVDs manufactured.

In the **Federal Register** of October 5, 2010 (75 FR 61494), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 502 of the FD&C Act/Section 351 of the PHS Act	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Glossary	689	1	689	4	2,756

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–74 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0610]

Draft Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic." The draft guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic. The agency makes recommendations to industry for focusing limited resources on reports

related to products indicated for the prevention and treatment of influenza and other specific types of reports indicated in the draft guidance. This draft guidance is a revision of the draft guidance for industry of the same title published on December 16, 2008.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 8, 2011. Submit written comments on the proposed collection of information by March 8, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding pandemic influenza: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4146, Silver Spring, MD 20993–0002, 301–796–8510.

Regarding human drug products: Solomon Iyasu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4447, Silver Spring, MD 20993–0002, 301–796–2370.

Regarding human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

Regarding medical device products: Deborah Moore, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3230, Silver Spring, MD 20993–0002, 301–796–6106.

Regarding dietary supplements: John Sheehan, Center for Food Safety and Applied Nutrition (HFS–315), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1488.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic." In the **Federal Register** of December 16, 2008 (73 FR 76364), FDA published notice of the availability of a draft guidance of the same title. FDA anticipates that during an influenza pandemic, industry and FDA workforces may be reduced while reporting of adverse events related to widespread use of medical products indicated for the treatment and prevention of influenza may increase, although the extent of these possible changes is unknown. The revised draft guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic.

II. Revisions to the 2008 Draft Guidance

FDA is issuing a revised draft guidance that includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The revised draft guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events and a plan for the submission of stored reports that were not submitted within regulatory timeframes. The revised draft guidance recommends that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic do the following:

- Document the conditions that prevent them from meeting normal reporting requirements,
- Notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when these conditions exist and when the reporting process is restored, and
- Maintain records to identify what reports have been stored.

These recommendations represent collections of information under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) discussed in section IV of this document. In issuing this revised draft guidance, FDA considered all comments that were submitted in response to the December 2008 draft guidance. Most comments requested that greater clarity be provided in certain sections; FDA has revised these sections accordingly.

This draft guidance does not address monitoring and reporting of adverse events that might be imposed as a condition of authorization for products authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb–3). This draft guidance also does not address monitoring and reporting of adverse events as required by regulations establishing the conditions for investigational use of drugs, biologics, and devices. (*See* 21 CFR parts 312 and 812.)

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on postmarketing adverse event reporting for medical products and dietary supplements during pandemic influenza. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

The draft guidance explains FDA's approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic, including an intent not to object to changes in the timing of submission of certain reports during some stages of the pandemic response. The Agency recommends that each firm's pandemic influenza COOP include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The draft guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) Maintain documentation of the conditions that prevent them from meeting normal reporting requirements, (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist and when the reporting process is restored, and (3) maintain records to identify what reports have been stored.

Based on the number of manufacturers that would be covered by the draft guidance, we estimate that approximately 5,000 firms will add to their COOP: (1) Instructions for reporting adverse events and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year, and that each notification will take approximately 8 hours to prepare and submit.

Concerning the recommendation in the draft guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements and also maintain records to identify what adverse event reports have been stored and when the reporting process is restored, we estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and that approximately 500 firms will each need approximately 8 hours to maintain the records. Therefore, the total recordkeeping burden that would result from the draft guidance would be 258,000 hours.

The draft guidance also refers to previously approved collections of information found in FDA's adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and part 803. These regulations contain collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and are approved under OMB control numbers 0910–0116, 0910–0291, 0910–0230, 0910–0308, 0910–0437, and 0910–0543. In addition, the draft guidance also refers to adverse event reports for nonprescription human drug products marketed without an approved application and dietary supplements required under sections 760 and 761 of the FD&C Act (21 U.S.C. 379aa and 379aa–1), which include collections of information approved under OMB control numbers 0910–0636 and 0910–0635.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
Notify FDA when normal reporting is not feasible	500	1	500	8	4,000
Total					4,000

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

	Number of recordkeepers	Number of records per recordkeeping	Total records	Hours per record	Total hours
Add adverse event reporting plan to COOP	5,000	1	5,000	50	250,000
Maintain documentation of influenza pandemic conditions and resultant high absenteeism	500	1	500	8	4,000
Maintain records to identify what reports have been stored and when the reporting process was restored	500	1	500	8	4,000
Total					258,000

[1] There are no capital costs or operating and maintenance costs associated with this information collection.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm,* or *http://www.regulations.gov.*

Dated: *January 3, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–94 Filed 1–6–11; 8:45 am]

BILLING CODE 4110–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0643]

Draft Guidance for Industry on Electronic Source Documentation in Clinical Investigations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Electronic Source Documentation in Clinical Investigations." This document provides guidance to sponsors, contract research organizations (CROs), data management centers, and clinical investigators on capturing, using, and archiving electronic data in FDA-regulated clinical investigations. It also describes FDA's recommended procedures for ensuring the reliability, quality, integrity, and traceability of electronic source data and source records maintained at the site for FDA inspection.

DATES: Although you can comment on any guidance at any time (*see* 21 CFR 10.115(g)(5)), to ensure that FDA considers your comments on the draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by April 7, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4173, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Leonard Sacks, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 32, rm. 4174, Silver Spring, MD 20993–0002, 301–796–8502.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Electronic Source Documentation in Clinical Investigations." This guidance is intended to be used together with the guidances for industry [1] entitled:

- *Computerized Systems Used in Clinical Investigations,*
- *Part 11, Electronic Records; Electronic Signatures—Scope and Application,* and
- *General Principles of Software Validation; Final Guidance for Industry and FDA Staff.*

With the increasing use of computerized systems in clinical investigations, it is common to find source data documented in an electronic format, *e.g.,* clinical data initially documented in electronic health records maintained by hospitals and institutions, electronic case report forms, laboratory reports that are electronically generated, electronic medical images from devices, and electronic diaries provided by study subjects. When paper source documents are available for review, tracing of data in paper-based studies can be performed easily. However, when source data is electronic, the data is traced through complex data capture, transmission, and archival processes. This guidance recommends practices that will help ensure that electronic source data and source records are accurate, legible, original, attributable (*e.g.,* user name and password), and contemporaneously entered; and meet the regulatory requirements for recordkeeping and retention.

The following specific topics related to electronic source data are discussed:

- The identification of the *data element* as the basic unit of information in the electronic case report form;
- The description of a source of each data element;
- Information about the electronic creation, modification, transmission, and storage of source data and documents;
- Investigator responsibilities with respect to reviewing and archiving electronic data;
- Transmission of the data to the sponsor and/or other designated parties; and
- Preservation of data integrity.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on capturing, using, and archiving electronic data in FDA-regulated clinical investigations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 312.62(b) and 312.64(b) have been approved under OMB control number 0910–0014; and the collection of information in §§ 812.140 and 812.150 has been approved under OMB control number 0910–0078.

[1] FDA guidances are available on FDA's Web page at *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm.* FDA guidances are issued and updated regularly. We recommend you check the Web site to ensure that you have the most up-to-date version of a guidance.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* and *http://www.regulations.gov.*

Dated: January 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–73 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–1981–N–0361 (formerly 81N–0391), FDA–1981–N–0077 (formerly 81N–0393), FDA–1981–N–0248 (formerly 81N–0396), FDA–1982–N–0225 (formerly 82N–0078), FDA–1982–N–0046 (formerly 82N–0095), FDA–1982–N–0264 (formerly 82N–0096), FDA–1982–N–0310 (formerly 82N–0311), and FDA–1983–N–0137 (formerly 83N–0095); DESI 5213, 6290, 6303, 6514, 8658, 11935, and 12152]

Drugs for Human Use; Drug Efficacy Study Implementation; Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy; Withdrawal of Hearing Requests; Opportunity To Affirm Outstanding Hearing Requests; Final Resolution of Dockets

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to Docket Nos. 81N–0391, 82N–0078, and 82N–0311 have been withdrawn and therefore, shipment in interstate commerce of the products identified in those dockets, or any identical, related, or similar product that is not the subject of an approved new drug application (other than an over-the-counter (OTC) product that complies with an applicable OTC monograph), is unlawful as of the effective date of this notice. FDA is also offering an opportunity to affirm outstanding hearing requests in Docket Nos. 81N–0393, 81N–0396, 82N–0095, 82N–0096, and 83N–0095. FDA will assume that companies with outstanding hearing requests that do not respond to this notice are no longer interested in pursuing their requests, and will deem the requests withdrawn.

DATES: *Effective Date:* This notice is effective February 7, 2011. Hearing requests must be affirmed by notifying FDA by February 7, 2011. Hearing requests not affirmed within that time frame will be deemed withdrawn.

ADDRESSES: All communications in response to this notice should be identified with the appropriate docket number, and directed to the appropriate office listed as follows:

To affirm or withdraw hearing requests: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993–0002.

All other communications: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993–0002, 301–796–3349, e-mail: *sakineh.walther@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (FD&C act) required that "new drugs" be approved for safety by FDA before they could legally be sold in interstate commerce.[1] To this end, the FD&C Act made it the sponsor's responsibility, prior to marketing a new drug, to submit a new drug application (NDA) to FDA to prove that its drug was safe. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS)[2] to the approved drug to be "covered" by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the act to require that new drugs be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval. This amendment also necessitated that FDA conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The agency reviewed and re-evaluated the reports and published its findings in **Federal Register** notices. FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

In the early 1970s, FDA granted temporary exemptions[3] from the time limits established[4] for completing certain phases of the DESI program for certain oral prescription drugs offered for relief of cough, cold, allergy, and related symptoms. The exemptions were granted because of the close relationship between these prescription drugs and drugs sold over the counter (OTC) that were subject to the ongoing OTC drug review (*see* 21 CFR part 330). Postponement of final evaluations of these DESI prescription products enabled the agency to consider the recommendations of the OTC review panel in addition to any evidence submitted by NDA holders and other parties in response to various DESI notices covering relevant products.

All drugs covered by the DESI review are "new drugs" under the FD&C Act. If FDA's final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for such indications, provided

[1] A "new drug" is defined by the FD&C Act as a drug that "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this FD&C Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use * * *." (21 U.S.C. 321(p)).

[2] Section 310.6(b)(1) (21 CFR 310.6(b)(1)) provides: "An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties."

[3] 38 FR 34481 (December 14, 1973).

[4] 38 FR 4006 (February 9, 1973) and 37 FR 15022 (July 27, 1972).

it is the subject of an application approved for safety and effectiveness. Sponsors of drug products that have been found to be effective for one or more indications through the DESI process may rely on FDA's effectiveness determinations, but typically must update their labeling to conform to the indications found to be effective by FDA and to include any additional safety information required by FDA. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications if found to be effective under DESI; IRS drug products require an approved NDA or abbreviated new drug application (ANDA), as appropriate. Furthermore, labeling for drug products classified as effective may contain only those indications for which the review found the product effective unless the firm marketing the product has received an approval for the additional indication(s).

II. DESI Review of Oral Prescription Drugs Offered for Relief of Symptoms of Cough, Cold, or Allergy

A. DESI Cough, Cold, or Allergy Dockets for Which Hearing Requests Have Been Withdrawn

1. Tussionex Tablets and Suspension and Omni-Tuss Suspension, Docket 81N–0391 (DESI 6514)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22606), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness, and offered an opportunity for a hearing on a proposal to withdraw approval of the NDAs for the products.

Tussionex Tablets and Suspension, both containing dihydrocodeinone and phenyltoloxamine dihydrogen sulfate, were marketed under NDA 10–768, and labeled as antitussives. Omni-Tuss Suspension, containing codeine sulfate, phenyltoloxamine dihydrogen sulfate, chlorpheniramine maleate, ephedrine sulfate, and guaiacol carbonate, was marketed under NDA 12–666, and was also labeled as an antitussive.

In response to the May 25, 1982, notice, timely hearing requests were filed by Pennwalt Corp., 755 Jefferson Rd., Rochester, NY 14623, for its products marketed under NDA 10–768 [5], and Boots Pharmaceuticals, Inc., 6540 Line Ave., Shreveport, LA 71106–9989, for its product IRS to Omni-Tuss Suspension.

Pennwalt, the NDA holder for Omni-Tuss Suspension, did not request a hearing for that product. On May 24, 1983 (48 FR 23311), FDA announced that it was withdrawing approval of NDA 12–666, effective June 23, 1983. On February 29, 1988, Pennwalt withdrew its hearing request for the Tussionex products, following approval of a reformulation of the suspension product (NDA 19–111). On March 23, 1988 (53 FR 9492), FDA announced it was withdrawing approval of NDA 10–768, effective April 22, 1988. On May 23, 1988, Boots withdrew its hearing request.

Thus, all outstanding hearing requests related to Docket 81N–0391 have now been withdrawn and, as stated previously, the approvals for NDA 10–768 and NDA 12–666 were withdrawn in 1988 and 1983, respectively. Shipment in interstate commerce of the previously mentioned products, or any IRS product that is not the subject of an approved NDA or ANDA, is unlawful as of the effective date of this notice. This notice is not applicable to OTC products that comply with an OTC monograph (21 CFR 310.6(f)). Any person who wishes to determine whether a specific product is covered by this notice should write to the Center for Drug Evaluation and Research (address given previously).

2. Hycodan Syrup, Tablets, and Powder; Benadryl With Ephedrine Sulfate Kapseal; Chlor-Trimeton Repetabs Tablets; PBZ Lontabs and PBZ–SR; Dimetane Extentabs; Hispril Spansule Capsules; Disophrol Tablets; and Novrad with A.S.A. Pulvules; Docket 82N–0078 (DESI 5213, 6290, 6303, 8658, 11935)

In a notice published in the **Federal Register** on June 1, 1982 (47 FR 23809), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness for certain indications, and offered an opportunity for a hearing on a proposal to withdraw approval of the NDAs for those indications.

Hycodan Syrup, Tablets, and Powder, containing hydrocodone bitrartrate and homatropine methylbromide, were marketed under NDA 5–213. Benadryl with Ephedrine Sulfate Kapseal, containing diphenhydramine hydrochloride and ephedrine sulfate, was marketed under NDA 5–845. Chlor-Trimeton Repetabs Tablets, containing 12 milligrams (mg) chlorpheniramine maleate, were marketed under NDA 7–638. PBZ Lontabs and PBZ–SR, containing tripelennamine hydrochloride, were marketed under NDA 10–533. Dimetane Extentabs, containing brompheniramine maleate, was marketed under NDA 10–799. Hispril Spansule Capsules, containing diphenylpyraline hydrochloride, was marketed under NDA 11–945. Disophrol Tablets, containing dexbrompheniramine maleate and pseudoephrine sulfate, was marketed under NDA 12–394. Novrad with A.S.A. Pulvules, containing levopropoxyphene napsylate and aspirin, was marketed under NDA 13–097.

In response to the June 1, 1982, notice, timely hearing requests were filed by Cord Laboratories, Inc., 2555 W. Midway Blvd., Broomfield, CO 80020, for its IRS products Chlorpheniramine Maleate S.R. Capsules and Efedra-PA Tablets, and KV Pharmaceutical Co., 2503 South Hanley Rd., St. Louis, MO 63144, for its IRS products chlorpheniramine maleate sustained release capsules, 8 and 12 mg. A late hearing request was filed by Sidmak Laboratories, 17 West St., P.O. Box 371, East Hanover, NJ 07936, for three IRS products: Chlorpheniramine maleate 8 mg.; chlorpheniramine maleate 12 mg; and a dexbrompheniramine maleate and pseudoephedrine sulfate product.

NDAs 5–213, 5–845, and 7–638 have not been withdrawn, but the products marketed under NDA 5–213 and NDA 7–638 have been discontinued, and the oral Benadryl products associated with NDA 5–845 are marketed with indications that are consistent with the OTC monograph, 21 CFR part 341. NDAs 10–533, 10–799, 11–945, and 12–394 were voluntarily withdrawn on November 7, 2007 (72 FR 62858), June 16, 2006 (71 FR 34940), March 21, 1994 (59 FR 9989), and October 9, 1986 (51 FR 36295), effective on December 7, 2007, June 16, 2006, April 1, 1994, and November 10, 1986, respectively. On June 7, 1977, FDA announced that it was withdrawing approval of NDA 13–097, effective June 13, 1977, for failure to file required reports (42 FR 29104). NDA 13–097 was included in

[5] This **Federal Register** notice identifies the products that are the subjects of hearing requests to the extent possible based on the information contained in the hearing requests. In some cases, the companies requesting hearings identified the product that was the subject of the hearing request by name. In other cases, the company simply identified the subject of its hearing request as a product that is IRS to one of the products reviewed under DESI. In yet other cases, there is no information provided by the requester about the product that is the subject of its hearing request.

the June 1982 notice to inform manufacturers of IRS products of the agency's finding of effectiveness for the product (42 FR 23809).

On October 21, 2009, the hearing request filed by Cord Laboratories, Inc., was withdrawn by its successor-in-interest, Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020. On December 4, 2009, KV Pharmaceutical Co. also withdrew its hearing request. On February 15, 2010, Sidmak Laboratories' hearing request was withdrawn by its successor-in-interest, Teva Pharmaceuticals. Thus, all outstanding hearing requests related to Docket 82N–0078 have now been withdrawn.

Shipment in interstate commerce of the previously mentioned products, or any IRS product that is not the subject of an approved NDA or ANDA, is unlawful as of the effective date of this notice. This notice is not applicable to OTC products that comply with an OTC monograph (21 CFR 310.6(f)). Any person who wishes to determine whether a specific product is covered by this notice should write to the Center for Drug Evaluation and Research (address given previously).

3. Actifed Syrup and Tablets; Docket 82N–0311 (DESI 11935)

In a notice published in the **Federal Register** on October 22, 1982 (47 FR 47085), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. In the notice, FDA also announced the conditions for marketing these products for the indication for which they were regarded as effective, and offered an opportunity for a hearing concerning a proposal to withdraw approval of the NDAs for the indications reclassified to lacking substantial evidence of effectiveness.

Actifed Syrup and Tablets both contained triprolidine hydrochloride and pseudoephedrine hydrochloride, and were marketed under NDA 11–935 and NDA 11–936, respectively.

In response to the October 22, 1982, notice, timely hearing requests were filed by Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, for its IRS products Corphed Syrup and Tablets, and Lemmon Co., 850 Cathill Rd., Sellersville, PA 18960, for its IRS products Tri-Fed and Actiprem. A late hearing request was filed by Sidmak Laboratories, Inc., 17 West St., P.O. Box 371, East Hanover, NJ 07936, for its product IRS to Actifed Tablets.

On May 26, 1983, Lemmon Co. withdrew its hearing request relating to this docket. Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, the successor-in-interest to Cord Laboratories, Inc., withdrew its hearing request on October 21, 2009. On February 15, 2010, Teva Pharmaceuticals, the successor-in-interest to Sidmak Laboratories, withdrew its hearing request. Thus, all outstanding hearing requests related to Docket 82N–0311 have now been withdrawn. NDAs 11–935 and 11–936 were withdrawn by FDA on November 28, 1997, effective December 29, 1997, following requests by the application holders. (62 FR 63347).

Shipment in interstate commerce of the previously mentioned products, or any IRS product that is not the subject of an approved NDA or ANDA, is unlawful as of the effective date of this notice. This notice is not applicable to OTC products that comply with an OTC monograph (21 CFR 310.6(f)). Any person who wishes to determine whether a specific product is covered by this notice should write to the Center for Drug Evaluation and Research (address given above).

B. DESI Cough, Cold, or Allergy Dockets With Outstanding Hearing Requests

In 2006, FDA announced a new drug safety initiative to address unapproved drugs currently being marketed in the United States, and to facilitate a rational process to bring all such unapproved drugs into the approval process. As part of the Unapproved Drugs Initiative, the Office of Compliance of the Center for Drug Evaluation and Research is reviewing proceedings that remain open under DESI. According to FDA's records, the dockets discussed below contain pending hearing requests. In cases where FDA was able to obtain current contact information for a company (or its successor-in-interest) or its representative, FDA sent letters directly to the companies (or their successors-in-interest) and/or their representatives requesting that outstanding hearing requests be withdrawn or affirmed within a specified time frame. In some cases, however, FDA was unable to find current contact information for the companies that requested hearings. Because many of the products that are the subjects of these hearing requests may no longer be marketed [6] and some of the companies that requested hearings may no longer be in business, FDA is seeking to determine whether there is continued interest in pursuing these outstanding hearing requests.

Through this **Federal Register** notice, FDA seeks to have any company with an outstanding hearing request covered by this notice that has not already responded to a direct communication from FDA either withdraw or affirm its hearing request. FDA will assume that companies with outstanding hearing requests that do not respond to this notice are no longer in business and/or do not have a continuing interest in the hearings, and FDA will deem their requests withdrawn.

To withdraw an outstanding hearing request, a company (or its successor-in-interest) or its representative should send a letter stating its intention to do so to the address provided above. The letter should include the docket number of the proceeding, as well as the name and NDC (National Drug Code) number of the product that is the subject of the hearing request.

To affirm an outstanding hearing request, a company (or its successor-in-interest), or its representative should send a letter stating its intention to do so to the address provided previously. The letter should include the docket number of the proceeding, as well as the name and NDC number of the product that is the subject of the hearing request. Letters affirming outstanding hearing requests must be postmarked or e-mailed within 30 calendar days of the date of this notice. Only currently outstanding hearing requests may be affirmed; this notice does not provide a new opportunity to request a hearing under any of these dockets.

1. Phenergan Expectorant With Codeine, Phenergan VC Expectorant Plain, Phenergan VC Expectorant With Codeine, Phenergan Expectorant Plain, and Pediatric Phenergan Expectorant With Dextromethorphan; Docket 81N–0393 (DESI 6514)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22610), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness, and offered an opportunity for a hearing

[6] For example, many of the products covered by these dockets, as originally formulated or as reformulated, contain phenylpropanolamine (PPA). In 2001, FDA proposed to withdraw several new drug applications for products containing PPA, due to evidence that the ingredient increases the risk of hemorrhagic stroke (66 FR 42665, August 14, 2001). FDA believes products containing PPA are no longer being marketed.

on a proposal to withdraw approval of the NDAs for the products.

Phenergan Expectorant With Codeine, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and codeine phosphate, was marketed under NDA 8–306. Phenergan VC Expectorant Plain, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and phenylephrine hydrochloride, was marketed under NDA 8–306. Phenergan VC Expectorant With Codeine, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, phenylephrine hydrochloride, and codeine phosphate, was marketed under NDA 8–306. Phenergan Expectorant Plain, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, and sodium citrate, was marketed under NDA 8–604. Pediatric Phenergan Expectorant With Dextromethorphan, containing promethazine hydrochloride, ipecac fluidextract, potassium guaiacolsulfonate, citric acid, sodium citrate, and dextromethorphan hydrobromide, was marketed under NDA 11–265. All of the products were marketed as expectorants.

In response to the May 25, 1982, notice, timely hearing requests were filed by Bay Laboratories, 3654 West Jarvis, Skokie, IL 60076, for its IRS products Promethazine Expectorant with Codeine, Promethazine VC Expectorant Plain, Promethazine VC Expectorant with Codeine, Promethazine Expectorant Plain, and Promethazine Pediatric Expectorant; Cord Laboratories, Inc., 2555 W. Midway Blvd., Broomfield, CO 80020, for two IRS products, the first a syrup containing codeine phosphate, promethazine hydrochloride, potassium guaiacolsulfonate, citric acid, anhydrous, sodium citrate, hydrous, and ipecac fluidextract and the second a syrup containing codeine phosphate, promethazine hydrochloride, phenylephrine hydrochloride, potassium guaiacolsulfonate, citric acid, anhydrous, sodium citrate, hydrous, and ipecac fluidextract; Lederle Laboratories, 401 N Middletown Rd., Pearl River, NY 10965, for its products IRS to the Phenergan products considered under this docket except for the pediatric formulation; National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to all five Phenergan products considered under this docket; Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207, for IRS products Promethazine HCl Expectorant VC with Codeine, Promethazine HCl Expectorant Plain, and Promethazine HCl Expectorant with Codeine; and Wyeth Laboratories, P.O. Box 8299, Philadelphia, PA 19101, the manufacturer of the Phenergan products, for all five of the Phenergan products considered under this docket.

On July 13, 1984, Wyeth, the holder of the NDAs for the Phenergan products, withdrew its hearing request after approval of reformulated versions of four of its five products. Accordingly, on August 15, 1984 (49 FR 32681), FDA announced that it was withdrawing approval of NDAs 8–306, 8–604, and 11–265 pertaining to the old formulations of the Phenergan products, effective September 14, 1984. On October 25, 1984, Cord also withdrew its hearing request relating to this docket, based on discontinuation of the products that were the subject of the hearing request.

FDA sent letters to Pfizer, Inc., 235 East 42nd St., New York, NY 10017, successor to Lederle Laboratories, and to Actavis, 60 Columbia Rd., Building B, Morristown, NJ 07960, successor to Purepac Pharmaceuticals, on November 16, 2010, requesting that these companies withdraw or affirm their outstanding hearing requests under this docket within 30 days. On December 7, 2010, Pfizer withdrew its hearing request. On December 10, 2010, Actavis withdrew its hearing request.

FDA was unable to find current contact information for Bay Laboratories and National Pharmaceuticals. If either of these companies, or its successor-in-interest, continues to have an interest in pursuing its hearing requests under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that hearing requests that are not affirmed within that time frame are no longer being pursued, and will deem them withdrawn.

2. Dimetane Expectorant, Dimetane Expectorant-DC, and Actifed-C Expectorant; Docket 81N–0396 (DESI 6514)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22609), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness, and offered an opportunity for a hearing on a proposal to withdraw approval of the NDAs for the products.

Dimetane Expectorant, containing brompheniramine maleate, phenylephrine hydrochloride, phenylpropanolamine hydrochloride, and guaifenesin, was marketed under NDA 11–694. Dimetane Expectorant-DC, containing codeine phosphate, brompheniramine maleate, phenylephrine hydrochloride, phenylpropanolamine hydrochloride, and guaifenesin, was marketed under NDA 11–694. Actifed-C Expectorant, containing codeine phosphate, triprolidine hydrochloride, pseudoephedrine hydrochloride, and guaifenesin, was marketed under NDA 12–575. All of these products were marketed as expectorants.

In response to the May 25, 1982, notice, timely hearing requests were filed by A.H. Robins Co., 1407 Cummings Dr., Richmond, VA 23220, for its products marketed under NDA 11–694; Bay Laboratories, 3654 West Jarvis, Skokie, IL 60076, for its IRS products Triphen Expectorant, Triphen Expectorant DC, and Pseudodine "C" Expectorant; Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709, for its product marketed under NDA 12–575; Cord Laboratories, Inc., 2555 W. Midway Blvd., Broomfield, CO 80020, for its IRS product, a syrup containing codeine phosphate, triprolidine hydrochloride, pseudoephedrine hydrochloride, and guaifenesin; Lederle Laboratories, 401 N. Middletown Rd., Pearl River, NY 10965, based on its distribution of Dimetane Expectorant; National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to Dimetane Expectorant, Dimetane Expectorant DC, and Actifed-C; and Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207, based on its distribution of an IRS product, Brompheniramine Maleate Expectorant.

On April 3, 1984, A.H. Robins, the holder of the NDA for Dimetane Expectorant and Dimetane Expectorant-DC, withdrew its hearing request after approval of reformulated versions of its products. Accordingly, on August 24, 1984 (49 FR 33726), FDA announced that it was withdrawing approval of those portions of NDA 11–694 pertaining to the old formulations of the Dimetane Expectorant products, effective September 24, 1984.

On September 14, 1984, FDA announced that it was withdrawing approval of those portions of NDA 12–575 pertaining to the old formulation of Actifed-C Expectorant (49 FR 36169), effective October 15, 1984, after the NDA holder, Burroughs Wellcome,

obtained approval for a reformulated version of the product and withdrew its hearing request. On October 25, 1984, Cord also withdrew its hearing request relating to this docket, based on discontinuation of the product that was the subject of the hearing request.

FDA sent letters to Pfizer, Inc., 235 East 42nd St., New York, NY 10017, successor to Lederle Laboratories, and to Actavis, 60 Columbia Rd., Building B, Morristown, NJ 07960, successor to Purepac Pharmaceuticals, on November 16, 2010, requesting that these companies withdraw or affirm their outstanding hearing requests under this docket within 30 days. On December 7, 2010, Pfizer withdrew its hearing request. On December 10, 2010, Actavis withdrew its hearing request.

FDA was unable to find current contact information for Bay Laboratories and National Pharmaceuticals. If either of these companies, or its successor-in-interest, continues to have an interest in pursuing its hearing request under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that hearing requests that are not affirmed within that time frame are no longer being pursued, and will deem them withdrawn.

3. Ambenyl Expectorant and Pyribenzamine and Ephedrine Tablets; Docket 82N–0095 (DESI 6514, 11935)

In a notice published in the **Federal Register** on May 25, 1982 (47 FR 22604), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these product, to remain on the market beyond the time limit established for DESI. The notice also reclassified the products to lacking substantial evidence of effectiveness, and offered an opportunity for a hearing on a proposal to withdraw approval of the NDAs for the products.

Ambenyl Expectorant, containing codeine sulfate, bromodiphenhydramine hydrochloride, diphenhydramine hydrochloride, ammonium chloride, potassium guaiacolsulfonate, and menthol, was marketed under NDA 9–319. Pyribenzamine and Ephedrine Tablets, containing tripelennamine hydrochloride and 12 mg ephedrine sulfate, were marketed under NDA 5–914.

In response to the May 25, 1982, notice, hearing requests were filed by Bay Laboratories, 3654 West Jarvis, Skokie, IL 60076, for Ambay Expectorant, its product IRS to Ambenyl Expectorant; Marion Laboratories, Inc., P.O. Box 9627, Kansas City, MO 64134, for its product marketed under NDA 9–319; and National Pharmaceuticals, Inc., 7205 Windsor Blvd., Baltimore, MD 21207, for its products IRS to Ambenyl Expectorant.

On May 24, 1983 (48 FR 23311), FDA announced that it was withdrawing approval of NDA 5–914 as it pertains to Pyribenzamine and Ephedrine Tablets, effective June 23, 1983, because no hearing was requested for the product by the NDA holder. On February 27, 1984, Marion Laboratories, the NDA holder for Ambenyl Expectorant, withdrew its hearing request after a reformulated version of its product was approved. Accordingly, on August 24, 1984 (49 FR 33726), FDA announced it was withdrawing approval of those portions of NDA 9–319 pertaining to the old formulation of Ambenyl Expectorant, effective September 24, 1984. On January 16, 1985, Bay Laboratories withdrew its hearing request relating to this docket.

FDA was unable to find current contact information for National Pharmaceuticals. If this company, or its successor-in-interest, continues to have an interest in pursuing its hearing request under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that if this hearing request is not affirmed within that time frame, it is no longer being pursued, and will deem it withdrawn.

4. Ornade Spansules; Docket 82N–0096 (DESI 12152)

In a notice published in the **Federal Register** on August 17, 1982 (47 FR 35870), FDA revoked the temporary exemption that permitted the drug product described below, and those products IRS to this product, to remain on the market beyond the time limit established for DESI. In the notice, FDA also announced the conditions for marketing these products, as reformulated, for the indication for which they were regarded as effective, and offered an opportunity for a hearing concerning a proposal to withdraw approval of the NDA with respect to the old formulation and the indications reclassified to lacking substantial evidence of effectiveness.

Ornade Spansules, as formulated early in the DESI review process, was a three-ingredient product containing 8 mg of chlorpheniramine maleate, 50 mg of phenylpropanolamine hydrochloride, and 2.5 mg of isopropamide, and was marketed under NDA 12–152. Prior to the publication of the August 17, 1982, **Federal Register** notice, Ornade Spansules was reformulated to be a controlled-release product containing 12 mg chlorpheniramine maleate and 75 mg phenylpropanolamine.

In response to the August 17, 1982, notice, timely hearing requests were filed by B.F. Ascher & Co., 15501 West 109th St., Lenexa, KS 66219, for its IRS product Drize Slow-Release Capsules; Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, for its IRS product Profenade #2 S.R. Capsules; Glaxo, Inc 1011 North Arendell Ave, PO Box 1217, Zebulon, NC 27597, for its IRS product Histabid Duracaps; SmithKline & French Laboratories, 1500 Spring Garden St., P.O. Box 7929, Philadelphia, PA 19101, for its product marketed under NDA 12–152; and Zenith Laboratories, Inc., 140 LeGrand Ave., Northvale, NJ 07647, for its IRS product, a sustained release product containing chlorpheniramine and phenylpropanolamine. Two late hearing requests were filed by Knoll Pharmaceutical Co. (formerly Boots Pharmaceuticals, Inc.), 300 Tri-State International Center, suite 200, Lincolnshire, IL 60069, for its IRS product Ru-Tuss Tablets, and Pioneer Pharmaceuticals, Inc., 209 40th St., Irvington, NJ 07111, for its IRS product, characterized by the company as a generic version of Ornade Spansules. A late hearing request was also filed by Sidmak Laboratories, Inc., 17 West St., P.O. Box 371, East Hanover, NJ 07936, for two IRS products, one containing chlorpheniramine maleate 12 mg and phenylpropanolamine, and the other containing chlorpheniramine maleate 8 mg and phenylpropanolamine.

On December 12, 1984 (49 FR 48387), FDA announced that it was withdrawing approval of those portions of NDA 12–152 covering the old, three-ingredient formulation for Ornade Spansules, effective January 11, 1985, noting that no party submitted a hearing request regarding the three-ingredient formulation. On January 15, 1986, SmithKline, the NDA holder for Ornade Spansules, withdrew its hearing request after receiving FDA approval for its supplemental NDAs covering the reformulated product. Knoll Pharmaceutical withdrew its hearing request relating to this docket on September 14, 1995.

On October 21, 2009, B.F. Ascher & Co. withdrew its hearing request relating to this docket. On the same date, Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, the successor-in-interest to Cord Laboratories, Inc., withdrew its hearing request. On February 15, 2010, Sidmak Laboratories' successor-in-interest, Teva

Pharmaceuticals, withdrew its hearing request.

On November 9, 2009, Glaxo's successor, GlaxoSmithKline, indicated it transferred its interest in Histabid Duracaps, the subject of its hearing request, to Medeva Pharmaceuticals sometime between 1984 and 1990, and GlaxoSmithKline indicated to the law firm that had filed the hearing request on behalf of Glaxo that it had no interest in pursuing the hearing request. The law firm was also able to contact UCB, the successor to the Celltech Chiroscience, which had previously acquired Medeva Pharmaceuticals. UCB also indicated to the law firm that had filed the hearing request that it had no interest in pursuing the hearing request filed by Glaxo for Histabid Duracaps. As the agency has not heard from UCB formally, the agency is providing the company an opportunity to affirm its hearing request in writing by the date specified in this notice. FDA will assume that if this hearing request is not affirmed within that time frame the request is no longer being pursued, and will deem it withdrawn.

FDA sent a letter to Zenith Laboratories on November 16, 2010 requesting that the company withdraw or affirm its outstanding hearing requests under this docket within 30 days. As of December 13, 2010, Zenith Laboratories had not responded to FDA.

FDA was unable to find current contact information for Pioneer Pharmaceuticals, Inc. If this company, or its successor-in-interest, continues to have an interest in pursuing its hearing request under this docket, the company (or its successor-in-interest) must affirm its hearing request in writing by the date specified in this notice. FDA will assume that if this hearing request is not affirmed within that time frame the request is no longer being pursued, and will deem it withdrawn

5. Dimetapp Extentabs and Elixir; Docket 83N–0095 (DESI 11935)

In a notice published in the **Federal Register** on December 23, 1983 (48 FR 56854), FDA revoked the temporary exemption that permitted the drug products described below, and those products IRS to these products, to remain on the market beyond the time limit established for DESI. In the notice, FDA also announced the conditions for marketing these products, as reformulated, for the indication for which they were regarded as effective, and offered an opportunity for a hearing concerning a proposal to withdraw approval of the NDAs for the old formulations and for the indications reclassified to lacking substantial evidence of effectiveness.

Dimetapp Extentabs, as formulated during the period of the DESI review, was a controlled-release product containing 12 mg brompheniramine maleate, 15 mg phenylephrine hydrochloride, and 15 mg phenylpropanolamine hydrochloride, and marketed under NDA 12–436. At the time of the publication of the December 23, 1983, **Federal Register** notice, the manufacturer had submitted a supplemental application proposing to reformulate the product to contain 12 mg brompheniramine maleate and 75 mg phenylpropanolamine hydrochloride in a controlled-release form. Dimetapp Elixir was originally formulated to contain 4 mg brompheniramine maleate, 5 mg phenylephrine hydrochloride, and 5 mg phenylpropanolamine hydrochloride per 5 milliliters (mL), and was marketed under NDA 13–087. At the time of the publication of the December 23, 1983, **Federal Register** notice, the manufacturer had submitted a supplemental application proposing to reformulate the product to contain 4 mg brompheniramine maleate and 25 mg phenylpropanolamine hydrochloride per 5 mL. The supplements to NDA 12–436 and NDA 13–087 were subsequently approved by FDA on April 20, 1984, and March 29, 1984, respectively.

In response to the December 23, 1983, notice, timely hearing requests were filed by A.H. Robins, 1407 Cummings Dr., Richmond, VA 23220, for its products marketed under NDA 12–436 and NDA 13–087; American Therapeutics, Inc., 75 Carlough Rd., Bohemia, NY 11716, for its product IRS to Dimetapp Extentab Tablets; Amide Pharmaceutical, Inc., 101 East Main St., Little Falls, NJ 07424, for its IRS product Ami-Tapp; Bay Laboratories, Inc., 3654 West Jarvis, Skokie, IL 60076, for Triphen Elixir, its product IRS to Dimetapp Elixir; Carnrick Laboratories, Inc., 65 Horse Hill Rd., Cedar Knolls, NJ 07927, for Nolamine Timed Release Tablets, its product IRS to Dimetapp Extentabs; Copley Pharmaceutical, Inc., 398 West Second St., P.O. Box 107, Boston, MA 02127, for its products IRS to Dimetapp Extentabs; Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, for Cordamine-PA Tablets, its product IRS to Dimetapp Extentabs; D.M. Graham Laboratories, Inc., Hobart, NY 13788, for unspecified IRS products; Forest Laboratories, Inc., 909 Third Ave., New York, NY 10022, for its IRS products Brocon C.R. Tablets and Chewable Brocon Tablets; Halsey Drug Co. Inc., 1827 Pacific St., Brooklyn, NY 11233, for its products IRS to Dimetapp Extentabs and Dimetapp Elixir; Lemmon Co., 850 Cathill Rd., Sellersville, PA 18960, for Phenatapp, its product IRS to Dimetapp Extentabs; LuChem Pharmaceuticals, Inc., P.O. Box 6038, 8910 Linwood Ave., Shreveport, LA 71136, for its IRS products Ban-Tuss HC, Ban-Tuss C Expectorant, Tuss-Delay Tablets, Ban-Tuss Plain, Klerist-D Tablets, Respergen, Am-Tuss Liquid, Novadyne DH, Novadyne Expectorant, Dexophed Tablets, Chem-Tuss-SR, Chem-Tuss Elixir, Chem-Tuss DM, Chem-Tuss DME, and Chem-Tuss N; Mayrand Inc., 4 Dundas Circle, P.O. Box 8860, Greensboro, NC 27419, for its products IRS to Dimetapp Extentabs and Dimetapp Elixir; National Pharmaceutical Manufacturing Co., 7205 Windsor Blvd., Baltimore, MD 21207, for its product IRS to Dimetapp Elixir; Pharmaceutical Basics, Inc., 301 S. Cherokee, Denver, CO 80223, for its IRS product Basamine S.R. Tablets; Pioneer Pharmaceuticals, Inc., 209 40th St., Irvington, NJ 07111, for Pioten Tablets, its product IRS to Dimetapp Extentabs; Quantum Pharmics, Ltd., 26 Edison St., Amityville, NY 11701, for its IRS product, Brom-Tapp; Superpharm Corp., 155 Oval Dr., Central Islip, NY 11722, for its product IRS to Dimetapp Extentab Tablets; United States Trading Corp., 10718 McCune Ave., Los Angeles, CA 90034, for its products IRS to Dimetapp Extentabs; and Upsher-Smith Laboratories, Inc., 14905 23rd Ave. North, Minneapolis, MN 55441, for unspecified products. A late hearing request was filed by Sidmak Laboratories, Inc., 17 West St., P.O. Box 371, East Hanover, NJ 07936, for its products IRS to Dimetapp Extentabs.

On June 11, 1985, A.H. Robins, the NDA holder for Dimetapp Extentabs and Dimetapp Elixir, withdrew its hearing request relating to this docket, after reformulating its products to comply with the OTC monograph in part 341 (21 CFR part 341), "Cold, Cough, Allergy, Bronchodilator, and Antihistamine Drug Products for Over-the-Counter Human Use." Accordingly, on July 19, 1985 (50 FR 29484), FDA announced that it was withdrawing approval of those portions of NDAs 12–436 and 13–087 pertaining to the old formulations of the Dimetapp products, effective August 19, 1985.

On August 23, 1984, Lemmon Co. withdrew its hearing request relating to this docket. Sandoz, Inc., 2555 West Midway Blvd., Broomfield, CO 80020, the successor-in-interest to Cord Laboratories, Inc., withdrew its hearing request on October 21, 2009. Forest Laboratories, Inc., withdrew its hearing request on October 22, 2009. The

hearing request filed by D.M. Graham Laboratories, Inc., was withdrawn on December 10, 2009. D.M. Graham Laboratories was previously acquired by Mallinckrodt, Inc., which is now part of Covidien, 172 Railroad Ave., Hobart, NY 13788. Teva Pharmaceuticals, the successor-in-interest to Sidmak Laboratories, withdrew its hearing request on February 15, 2010. Acura Pharmaceutical Co., 616 N. North Court, Palantine, IL 60067, successor to Halsey Drug Co., withdrew its hearing request on November 23, 2010.

FDA sent a letter to Merz Pharmaceuticals, LLC, P.O. Box 18806, Greensboro, NC 27419, successor to Mayrand, Inc., Pharmaceuticals, on November 16, 2010, requesting that this company withdraw or affirm its outstanding hearing request under this docket within 30 days. As of December 13, 2010, the company had not responded to FDA.

FDA was unable to find current contact information for American Therapeutics, Amide Pharmaceutical, Inc., Bay Laboratories, Inc., National Pharmaceutical Manufacturing Co., Pharmaceutical Basics, Inc., Superpharm Corp., and United States Trading Corp. FDA did not receive any response to its attempt to contact Carnrick Laboratories, a subsidiary of Elan Corporation; Copley Pharmaceutical, Inc.; LuChem Pharmaceuticals, Inc.; Pioneer Pharmaceuticals, Inc.; Quantum Pharmics, Ltd.; or Upsher-Smith Laboratories, Inc. If any of these companies, or their successors-in-interest, continue to have an interest in pursuing their hearing requests under this docket, the companies (or their successors-in-interest) must affirm their hearing requests in writing by the date specified in this notice. FDA will assume that hearing requests that are not affirmed within that time frame are no longer being pursued, and will deem them withdrawn.

III. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the FD&C Act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent to Sakineh Walther (*see* **ADDRESSES**).

Firms should also update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products. FDA plans to rely on its existing records, including drug listing records or other available information, when it targets violations for enforcement action. Firms should be aware that, after the effective date of this notice, FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice that is not the subject of an ongoing DESI proceeding.

IV. Reformulated Products

Some of the active ingredients found in drug products covered by this notice are included in the OTC monograph in part 341 (21 CFR part 341), "Cold, Cough, Allergy, Bronchodilator, and Antihistamine Drug Products for Over-the-Counter Human Use." OTC products that comply with this monograph may be marketed without approval.

However, FDA cautions firms against reformulating products into OTC products or different unapproved new drugs that are marketed under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combination of active ingredients have the potential to confuse health care practitioners and harm patients.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 502 and 505 (21 U.S.C. 352 and 355), and under authority delegated to the Assistant Commissioner for Policy under section 1410.21 of the FDA Staff Manual Guide.

Dated: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–104 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0247]

FDA Transparency Initiative: Improving Transparency to Regulated Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: As part of the third phase of the Transparency Initiative, the Food and Drug Administration (FDA) is announcing the availability of a report entitled "FDA Transparency Initiative: Improving Transparency to Regulated Industry." The report includes 19 action items and 5 draft proposals to improve transparency to regulated industry. FDA is seeking public comment on the content of the draft proposals, as well as on which draft proposals should be given priority.

DATES: Submit electronic or written comments by March 8, 2011.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets at the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ann Witt, Office of Policy, Planning, and Budget, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 32, rm. 4226, Silver Spring, MD 20993, 301–796–7463, FAX: 301–847–8616, e-mail: *Ann.Witt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the FDA Transparency Initiative

In January 2009, President Obama issued a memorandum on Transparency and Open Government calling for an "unprecedented level of openness in Government" and directing the Director of the Office of Management and Budget (OMB) to issue an Open Government Directive instructing executive departments and agencies to take specific actions to implement the principles of transparent, collaborative, and participatory government. The Open Government Directive was issued December 8, 2009. Under the leadership of Secretary of Health and Human Services, Kathleen Sebelius, the U.S. Department of Health and Human Services has also prioritized transparency and openness. In June 2009, the Commissioner of Food and Drugs (the Commissioner), Dr. Margaret Hamburg, launched FDA's Transparency Initiative to implement these efforts at FDA.

The initiative is overseen by a Task Force representing key leaders of FDA. The internal Task Force is chaired by the Principal Deputy Commissioner of FDA and includes five of the Agency's

center directors, the Chief Counsel, the Associate Commissioner of Regulatory Affairs, and the Chief Scientist. The Task Force is charged with submitting a written report to the Commissioner on the Task Force's findings and recommendations.

The Task Force has held two public meetings,[1] launched an online blog (*http://fdatransparencyblog.fda.gov/*), and opened a docket. The online blog and the docket received over 1,500 comments. The blog, which is ongoing, has offered an opportunity for exchange about specific ideas for transparency at the Agency.

The Task Force is proceeding with the Transparency Initiative in three phases:

- Phase I: FDA Basics.
- Phase II: Public Disclosure.
- Phase III: Transparency to Regulated Industry.

Phase I is intended to provide the public with basic information about FDA and how the Agency does its work. In early January 2010, FDA launched a Web-based resource called *FDA Basics* (*http://www.fda.gov/fdabasics*). The resource now includes (1) 158 questions and answers about FDA and the products that the Agency regulates, (2) 9 short videos that explain various FDA activities, and (3) 14 conversations with FDA officials about the work of their offices. Each month, senior officials from FDA product centers and offices host online sessions about a specific topic and answer questions from the public about that topic. FDA uses the feedback provided by the public to update this resource.

Phase II relates to FDA's proactive disclosure of information the Agency has in its possession, and how to make information about Agency activities and decisionmaking more transparent, useful, and understandable to the public, while appropriately protecting confidential information. On May 19, 2010, FDA released a report that contains 21 draft proposals about expanding the disclosure of information by FDA while maintaining confidentiality for trade secrets and individually identifiable patient information.

The Task Force solicited comment on the content of the proposals, as well as on which draft proposals should be given priority, for 60 days. The Task Force is reviewing the comments received and will recommend specific proposals to the Commissioner for consideration. The Task Force's recommendations will consider feasibility and priority, considering other Agency priorities that require resources. Not all of these proposals will necessarily be implemented. Some may require changes in law or regulation; some may require a substantial amount of resources.

Phase III is the subject of this document and is described in more detail in section II of this document.

II. Phase III: Transparency to Regulated Industry

The third phase of the Transparency Initiative addresses ways FDA can become more transparent to regulated industry to foster a more efficient and cost-effective regulatory process.

Regulated industry provides the public with food, drugs, medical devices, cosmetics, and other widely used and important consumer products. FDA's mission is to protect and promote the public health through oversight of these products.

In order to succeed, FDA must clearly communicate standards and expectations to industry. Communicating requirements and expectations to industry in a more accessible manner promotes understanding of, and compliance with, rules set up to protect the supply of food and medical products.

In response to a request for input from FDA on this topic in March 2010 (75 FR 11893, March 12, 2010), regulated companies requested additional transparency about the standards to which their products are held, the process for soliciting guidance from the Agency, and the progress of regulatory efforts at the Agency. In the report, FDA outlines 19 action items and 5 draft proposals to improve transparency to regulated industry.

The Task Force is soliciting comment on the content of the five draft proposals, as well as on which draft proposals should be given priority, for 60 days. After considering public comment on the draft proposals, the Task Force will recommend specific proposals to the Commissioner for consideration. FDA will begin to implement the action items in the report in 2011.

III. Request for Comments

FDA is interested in receiving comments from the public about the content of the five draft proposals as well as on which draft proposals should be given priority. Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Identify the draft proposal which your comment addresses by the number assigned to that proposal. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–71 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

[1] Transcripts and the webcast from both public meetings are available on the FDA Web site, *http://www.fda.gov/transparency.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 8, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading "Resources for You", click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8532, email: *nicole.vesely@fda.hhs.gov*, or FDA

Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will hear updates on new drug applications (NDAs) and biologics license applications (BLAs) approved under 21 CFR 314.500 and 601.40 (subpart H and subpart E, respectively, accelerated approval regulations) prior to January 1, 2009. These updates will provide information related to the status of phase IV clinical studies and to difficulties associated with completion of phase IV commitments. Phase IV studies are postmarketing studies to confirm clinical benefit of a drug after it receives accelerated approval.

Specifically, the committee will receive updates on the following products: (1) BLA 125084, trade name ERBITUX (cetuximab), application submitted by Imclone Systems Inc., used in combination with the anticancer agent irinotecan and indicated for the treatment of epidermal growth factor receptor (EGFR)-expressing colorectal cancer that has metastasized (spread beyond the colon or rectum) in patients for whom chemotherapy using irinotecan alone is ineffective or less effective; (2) supplemental BLA (sBLA) 125011/24, trade name BEXXAR (tositumomab and Iodine I 131 tositumomab), application submitted by SmithKline Beecham Corp. doing business as (d/b/a) GlaxoSmithKline, indicated for the treatment of patients with varieties of non-Hodgkin's lymphoma known as CD20 antigen-expressing relapsed or refractory, low grade, follicular, or transformed non-Hodgkin's lymphoma, who have not received the drug Rituximab; (3) NDA 21–673, tradename CLOLAR (clofarabine) for intravenous infusion, application submitted by Genzyme Corp., indicated for the treatment of pediatric patients 1 to 21 years old with acute lymphoblastic leukemia (ALL) whose disease has not responded to or has relapsed following treatment with at least two prior chemotherapy regimens; (4) NDA 21–877, tradename ARRANON (nelarabine) Injection, application submitted by GlaxoSmithKline, indicated for the treatment of patients with types of leukemia or lymphoma known as T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens; (5) BLA 125147, tradename VECTIBIX (panitumumab), application submitted by Amgen Inc., indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens; and (6) sNDA 21–588/025, tradename GLEEVEC (imatinib mesylate) tablets, application submitted by Novartis Pharmaceuticals Corp., indicated for the adjuvant (additional) treatment of adult patients following complete gross resection (removal) of a form of cancer known as Kit (CD117) positive gastrointestinal stromal tumors (GIST).

Based on the updates provided, the committee will have a general discussion centering on possible ways to improve the planning and conduct of trials to confirm clinical benefit (post marketing requirements). The overall goal will be the optimization of the accelerated approval process with a focus on decreasing the amount of time to confirm (or fail to confirm) clinical benefit while continuing to provide early availability of promising oncology products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 25, 2011. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 14, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 18, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 3, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–32 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0633]

Determination of System Attributes for the Tracking and Tracing of Prescription Drugs; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Determination of System Attributes for the Tracking and Tracing of Prescription

Drugs." This public workshop is intended to provide a forum for discussing potential approaches toward a track and trace system and obtaining input from supply chain partners on attributes and standards for the identification, authentication, and tracking and tracing of prescription drug packages, and to further the Agency's goal of protecting public health by securing the drug supply chain against the introduction of counterfeit and other substandard drugs.

DATES: The public workshop will be held on February 15 and 16, 2011, from 9 a.m. to 5 p.m. Submit electronic or written comments on the posted information or on the workshop to the docket by April 16, 2011.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, room 1503, Silver Spring, MD 20993. To register for the public meeting, e-mail your registration information to *drug.trackandtrace@fda.hhs.gov.* See section III of this document for registration details. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–4830, e-mail: *connie.jung@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Since the formation of the first Counterfeit Drug Task Force in 2003, FDA has strongly advocated for a multi-layered approach to securing the supply chain and protecting consumers from the threats posed by counterfeit drugs. The ability to track and trace finished drug products in the supply chain plays a significant role in providing transparency and accountability in the drug supply chain. On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) was signed into law. Section 913 of this legislation created section 505D of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which requires the Secretary of Health and Human Services (the Secretary) to develop standards and identify and validate effective technologies for the purpose of securing the drug supply chain against counterfeit, diverted, subpotent, substandard, adulterated, misbranded, or expired drugs. In addition, section 505D of the FD&C Act directs the Secretary to consult with specific entities to prioritize and develop standards for identification, validation, authentication, and tracking and tracing of prescription drugs.

In March 2010, FDA issued a final guidance for industry which describes the Agency's current recommendation for standardized numerical identification (also known as serialization) for prescription drug packages (Standards for Securing the Drug Supply Chain—Standardized Numerical Identification for Prescription Drug Packages, Guidance for Industry—Final Guidance [1]). This guidance is intended to be the first of several steps that FDA may take to implement section 505D of the FD&C Act and further improve the security of the drug supply chain. As FDA continues to work on developing additional standards for securing the drug supply chain, the agency is seeking public input to ensure that we consider information regarding all supply chain participants.

II. Purpose of the Workshop

This public workshop is intended to explore approaches for achieving an effective and feasible track and trace system for finished prescription drug products from the supply chain stakeholder's point of view, including industry and the public, and to obtain views on system attributes and standards that would facilitate identification, authentication, and tracking and tracing of prescription drug packages. We intend to discuss with stakeholders the necessary elements to accomplish effective authentication and identify desirable features of a track and trace system. Participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives.

By February 4, 2011, FDA will post information on our Web site *(http://www.fda.gov/Drugs/DrugSafety/ucm169828.htm)* under "Standards Development for Prescription Drug Supply Chain Security." as follows:

- Workshop agenda,
- Workshop discussion topics.

III. How To Register for the Workshop

To register for the workshop either: (1) E-mail your registration information to *drug.trackandtrace@fda.hhs.gov* or (2) mail your registration information to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**). Registration information should include registrant name, company or organization, address, phone number, and email address. Registration requests should be received by February 1, 2011. Registration is free. Seats are limited. FDA may limit the numbers of participants from each organization based on space limitations. Registrants will receive confirmation upon acceptance for participation in the workshop. Onsite registration on the day of the meeting will be based on space availability on the day of the event starting at 8 a.m. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop on FDA's Web site at: *http://www.fda.gov/Drugs/DrugSafety/ucm169828.htm.* If you need special accommodations due to a disability, please contact Connie Jung (*see* **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

IV. Parking Information

If you are driving to FDA's White Oak Campus, you should proceed to the South East Surface Parking Lot to park your vehicle. Shuttle service is available from the bus shelters in the South East Lot to Building 1. The FDA campus is a Federal facility, therefore all meeting attendees must enter through Building 1 and follow security procedures.

Dated: *January 3, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–72 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

[1] *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the OMB for review under the Paperwork Reduction Act of 1995:

Proposed Project: Ryan White HIV/AIDS Program: Client-Level Data Reporting System: (OMB No. 0915–0323)—[Revision]

The Ryan White HIV/AIDS Program's client-level data reporting system, entitled the Ryan White HIV/AIDS Program Services Report or the Ryan White Services Report (RSR), was created in 2008 by the Health Resources and Services Administration (HRSA). It is designed to collect information from grantees, as well as their subcontracted services providers, funded under Parts A, B, C, and D, and the Part F Minority AIDS Initiative of the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Ryan White HIV/AIDS Program). The Ryan White HIV/AIDS Program provides Federal HIV/AIDS Programs in the Public Health Service (PHS) Act under Title XXVI with flexibility to respond effectively to the changing HIV epidemic, with an emphasis on providing life-saving and life-extending services for people living with HIV/AIDS across this country, as well as targeting resources to areas that have the greatest needs.

All parts of the Ryan White HIV/AIDS Program specify HRSA's responsibilities in the administration of grant funds, the allocation of funds, the evaluation of programs for the population served, and the improvement of the quality of care. Accurate records of the providers receiving Ryan White HIV/AIDS Program funding, the services provided, and the clients served, continue to be critical issues for the implementation of the legislation and are necessary for HRSA to fulfill its responsibilities.

The RSR provides data on the characteristics of Ryan White HIV/AIDS Program-funded grantees, their contracted service providers, and the clients being served with program funds. The Report is intended to support clinical quality management, performance measurement, service delivery, and client monitoring at the system and client levels. The reporting system consists of two online data forms, the Grantee Report and the Service Provider Report, as well as a data file containing the client-level data elements. Data are submitted annually.

The legislation specifies grantee accountability and linking performance to budget. The RSR is used to ensure compliance with the requirements of the legislation, to evaluate the progress of programs, to monitor grantee and provider performance, to measure the Government Performance and Results Act (GPRA) and the Performance Assessment Rating Tool (PART) goals, and to meet reporting responsibilities to the Department, Congress, and OMB.

In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected through the RSR is critical for HRSA, State and local grantees, and individual providers to assess the status of existing HIV-related service delivery systems to investigate trends in service utilization and to identify areas of greatest need.

The estimated average annualized hour burden is 17,975 hours per year. Burden estimates are broken down into burden to grantee respondents and burden to service provider respondents. Estimates for grantees and service providers are further divided by the RSR component. Estimates for grantees and providers are based on prior experience in collecting, maintaining, and reporting data using the RSR and interviews with volunteers from grantee agencies.

The response burden for grantees is estimated as:

Component	Source of funding	Number of respondents	Responses per grantee	Hours per response	Total hour burden
Grantee Report	Part A	56	1	2.04	114
	Part B	59	1	2.52	149
	Part C	354	1	0.32	113
	Part D	98	1	0.33	32
	Subtotal	567			408

The response burden for service providers is estimated as:

Component	Number of respondents	Responses per provider	Total responses	Hours per response	Total hour burden
Service Provider Report	*2,080	1	*2,080	2.30	4,784

*All providers, including providers of administrative support services and direct client services.

Component	Electronic data system	Number of respondents	Responses per provider	Total responses	Hours per response	Total hour burden
Client Report	No	56	1	56	106.25	5,950
	Yes	1,822	1	1,822	3.75	6,832.5
	Subtotal	**1,878		**1,878		12,783

**Providers of direct client services only.

Total Burden is 17,975.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this **Federal Register** Notice to the desk officer for HRSA, either by e-mail to *OIRA—submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: January 3, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2011–99 Filed 1–6–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (Paperwork Reduction Act of 1995, as amended, 44 U.S.C. chapter 35), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Telephone Survey of Public Opinion Regarding Various Issues Related to Organ and Tissue Donation—[New]

The Division of Transplantation (DoT), Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), is planning to conduct a telephone survey of public knowledge, perceptions, opinion, and behaviors related to organ donation. Two key missions of the DoT are (1) to provide oversight for the Organ Procurement and Transplantation Network and policy development related to organ donation and transplantation and (2) to implement efforts to increase public knowledge, attitudes, and behaviors related to organ donation.

With a constantly growing deficit between the number of Americans needing donor organs (currently nearly 110,000) and the annual number of donors (14,632 in 2009), increasing the American public's willingness to donate becomes increasingly critical. Effective education and outreach campaigns need to be based on knowledge of the public's attitudes and perceptions about, and perceived impediments to, organ donation. Two national surveys using nearly identical survey instruments to identify public views and behaviors related to organ donation were conducted in 1993 and 2005.

The proposed study will identify current organ donation views and practices of the American public and various population subgroups using a survey instrument similar to the two earlier studies in order to track changes over time. It will measure issues such as level of public knowledge about donation, public intent to donate, impediments to public intent to donate, as well as attitudes about living donation, presumed consent, and financial incentives for donation. Demographic information also will be collected. The randomly drawn sample will consist of 3,000 adults (age 18 and over), including an oversample of Asians, Hispanics, African Americans, and Native Americans, and will be geographically representative of the United States. The survey instrument will be administered in English and Spanish languages through computer-assisted telephone interviews.

In addition to being useful to the DoT, especially in its donation outreach initiatives, results of this survey also will be of assistance to the transplant community, DoT grantees and other research efforts, and to the Secretary's Advisory Committee on Organ Transplantation (ACOT) as it fulfills its charge to advise the Secretary of Health and Human Services on the numerous and often controversial issues related to donation and transplantation. In its first meeting, the ACOT suggested such a survey to gather information to inform both public education efforts and policy decisions on the issue of organ donation.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Telephone survey	3,000	1	3,000	0.3	900
Total	3,000	1	3,000	0.3	900

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 3, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2011–100 Filed 1–6–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: February 8, 2011, 8:30 a.m. to 5 p.m. February 9, 2011, 8:30 a.m. to 5 p.m.

Place: L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024. Telephone: (202) 484–1000. Fax: (202) 646–4456.

Status: The meeting will be open to the public.

Purpose: The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

Agenda: The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels. Agenda items are subject to change as priorities indicate.

For Further Information Contact: Marcia Gomez, MD, Office of Special Population Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 594–4897.

Dated: January 3, 2011.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2011–98 Filed 1–6–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Children's Study Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Registration is required since space is limited and will begin at 8 a.m. Please visit the conference Web site for information on meeting logistics and to register for the meeting *http://www.circlesolutions.com/ncs/ncsac/index.cfm.* Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Children's Study Advisory Committee.

Date: January 26, 2011.

Time: 9 a.m. to 5 p.m.

Agenda: Topics to be discussed will include review of recruitment data to date and discussion on long-term stability of collected samples.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, E1/E2, Bethesda, MD 20892.

Contact Person: Kate Winseck, MSW, Executive Secretary, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5C01, Bethesda, MD 20892. (703) 902–1339. *ncs@circlesolutions.com*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. For additional information about the Federal Advisory Committee meeting, please contact Circle Solutions at *ncs@circlesolutions.com.*

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 3, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–127 Filed 1–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Multiplexed Assay Platforms for Protein Biomarkers of Cardiovascular Disease.

Date: January 24, 2011.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Kristin Goltry, PhD, Scientific Review Officer.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Research Project In Organ Failure.

Date: January 26, 2011.

Time: 1 p.m to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Roy L. White, PhD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7176, Bethesda, MD 20892–7924, 301–435–0310. *whiterl@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 3, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–118 Filed 1–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual other than conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: January 25, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate the Rehabilitation Medicine Department.

Place: National Institutes of Health, Building 10, 10 Center Drive, Room 4–2551, Bethesda, MD 20892.

Contact Person: David K. Henderson, MD, Deputy Director for Clinical Care, Office of the Director, Clinical Center, National Institutes of Health, Building 10, Room 6–1480, Bethesda, MD 20892. (301) 496–3515.

Dated: December 30, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–117 Filed 1–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: February 1, 2011.

Open: 8:30 a.m. to 12 p.m.

Agenda: To discuss administrative details relating to the Council's business and special reports.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Closed: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6, Bethesda, MD 20892.

Contact Person: Laura K. Moen, PhD, Director, Division of Extramural Research Activities, NIAMS/NIH, 6701 Democracy Blvd., Ste 800, Bethesda, MD 20892. 301–451–6515. *moenl@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: December 30, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–116 Filed 1–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the NIH Advisory Board for Clinical Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended to discuss personnel matters, the disclosure of which would constitute a clearly unwarranted invasion of privacy.

Name of Committee: NIH Advisory Board for Clinical Research.

Date: January 31, 2011.

Open: 10 a.m. to 1:15 p.m.

Agenda: To review the 2011 Clinical Center Strategic and Annual Operating Plan and provide updates on selected organizational initiatives.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4–51, Bethesda, MD 20892.

Closed: 1:15 p.m. to 2 p.m.

Agenda: To review and evaluate personnel matters.

Place: National Institutes of Health, Building 10, 10 Center Drive, CRC Medical Board Room 4–2551, Bethesda, MD 20892.

Contact Person: Maureen E. Gormley, Executive Secretary, Mark O. Hatfield Clinical Research Center, National Institutes of Health, Building 10, Room 6–2551, Bethesda, MD 20892. (301) 496–2897.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: December 30, 2010.

Anna P. Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–115 Filed 1–6–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2010–1127]

Application for Recertification of Prince William Sound Regional Citizens' Advisory Council

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Coast Guard announces the availability of, and seeks comments on, the application for recertification submitted by the Prince William Sound Regional Citizen's Advisory Council (PWSRCAC) for March 1, 2011, through February 29, 2012. Under the Oil Terminal and Tanker Environmental Oversight Act of 1990, the Coast Guard may certify on an annual basis, an alternative voluntary advisory group in lieu of a Regional Citizens' Advisory Council for Prince William Sound, Alaska. This advisory group monitors the activities of terminal facilities and crude oil tankers under the Prince William Sound program established by the statute. The current certification for PWSRCAC will expire February 28, 2011.

DATES: Public comments on PWSRCAC's recertification application must reach the Seventeenth Coast Guard District on or before February 22, 2011.

ADDRESSES: You may submit comments identified by docket number USCG–2010–1127 using any one of the following methods:

(1) Federal eRulemaking Portal: *http://www.regulations.gov.*

(2) Fax: 202–493–2251.

(3) Mail: Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey

Avenue, SE., Washington, DC 20590–0001.

(4) Hand delivery: Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this recertification, call or e-mail LCDR Mike Franklin, Seventeenth Coast Guard District (dpi); telephone (907) 463–2821; e-mail *Michael.R.Franklin@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Request for Comments

Public Participation and Request for Comments

We encourage you to participate in this application for recertification by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this notice of availability (USCG–2010–1127), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (via *http://www.regulations.gov*) or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online via *http://www.regulations.gov*, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov*, click on the "submit a comment" box, which will then become highlighted in blue. In the "Document Type" drop down menu select "Proposed Rule" and insert "USCG–2010–1127" in the "Keyword" box. Click "Search" then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8.5 by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may withhold recertification or grant a conditional recertification based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov*, click on the "read comments" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG–2010–1127" and click "Search." Click the "Open Docket Folder" in the "Actions" column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Public Meeting

The Coast Guard does not plan to hold a public meeting. But you may submit a request for one on or before February 5th, 2011 using one of the four methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid the process of thoroughly considering the application for recertification, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard published guidelines on December 31, 1992 (57 FR 62600), to assist groups seeking recertification under the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (33 U.S.C. 2732) (the Act). The Coast Guard issued a policy statement on July 7, 1993 (58 FR 36504), to clarify the factors that the Coast Guard would be considering in making its determination as to whether advisory groups should be certified in accordance with the Act; and the procedures which the Coast Guard would follow in meeting its certification responsibilities under the Act. Most recently, on September 16, 2002 (67 FR 58440), the Coast Guard changed its policy on recertification procedures for regional citizen's advisory council by requiring applicants to provide comprehensive information every three years. For the two years in between, applicants only submit information describing substantive changes to the information provided at the last triennial recertification. This is the year in this triennial cycle that PWSRCAC must provide comprehensive information.

At the conclusion of the comment period, February 22, 2011, the Coast Guard will review all application materials and comments received and will take one of the following actions:

(a) Recertify the advisory group under 33 U.S.C. 2732(o).

(b) Issue a conditional recertification for a period of 90 days, with a statement of any discrepancies, which must be corrected to qualify for recertification for the remainder of the year.

(c) Deny recertification of the advisory group if the Coast Guard finds that the group is not broadly representative of the interests and communities in the area or is not adequately fostering the goals and purposes of 33 U.S.C. 2732.

The Coast Guard will notify PWSRCAC by letter of the action taken on their respective applications. A notice will be published in the **Federal Register** to advise the public of the Coast Guard's determination.

Dated: December 27, 2010.

C.C. Colvin,

Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.

[FR Doc. 2011–88 Filed 1–6–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1874–DR; Docket ID FEMA–2010–0002]

Virginia; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Virginia (FEMA–1874–DR), dated February 16, 2010, and related determinations.

DATES: *Effective Date:* December 30, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Recovery Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Virginia is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of February 16, 2010.

The Independent City of Fredericksburg for emergency protective measures (Category B), including snow assistance, under the Public Assistance program for an additional 24-hour period during or proximate to the incident period (already designated for Public Assistance and emergency protective measures (Category B), including snow assistance, under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–134 Filed 1–6–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–1905–DR; Docket ID FEMA–2010–0002]

Virginia; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Virginia (FEMA–1905–DR), dated April 27, 2010, and related determinations.

DATES: *Effective Date:* December 30, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3886.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Virginia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of April 27, 2010.

Culpeper and Rappahannock Counties for emergency protective measures (Category B), including snow assistance, under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2011–133 Filed 1–6–11; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5477–N–01]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7262, Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: December 28, 2010.

Mark R. Johnston,

Deputy Assistant Secretary for Special Needs.

[FR Doc. 2010–33104 Filed 1–6–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–R–2010–N228; BAC–4311–K9–S3]

Back Bay National Wildlife Refuge, City of Virginia Beach, VA; Final Comprehensive Conservation Plan and Finding of No Significant Impact for Environmental Assessment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of our final comprehensive conservation plan (CCP) and finding of no significant impact (FONSI) for the environmental assessment (EA) for Back Bay National Wildlife Refuge (NWR). In this final CCP, we describe how we will manage this refuge for the next 15 years.

ADDRESSES: You may view or obtain copies of the final CCP and FONSI by any of the following methods. You may request a hard copy or CD–ROM.

Agency Web Site: Download a copy of the document(s) at *http://www.fws.gov/northeast/planning/Back%20Bay/ccphome.html.*

Electronic mail: northeastplanning@fws.gov. Include "Back Bay Final CCP" in the subject line of the message.

U.S. Postal Service: Thomas Bonetti, Natural Resource Planner, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035–9589.

In-Person Viewing or Pickup: Call 757–721–2412 to make an appointment during regular business hours at Back Bay NWR, 4005 Sandpiper Road, Virginia Beach, VA 23456–4325.

FOR FURTHER INFORMATION CONTACT: Jared Brandwein, Refuge Manager, Back Bay NWR, 4005 Sandpiper Road, Virginia Beach, VA 23456–4325; phone: 757–721–2412; electronic mail: *jared_brandwein@fws.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we finalize the CCP process for Back Bay NWR. We started this plan's development by publishing a notice in the **Federal Register** (67 FR 30950; May 8, 2002), and then updating that notice (72 FR 8196, February 23, 2007). We released the draft CCP/EA to the public, announcing and requesting comments in a notice of availability in the **Federal Register** (75 FR 15721) on March 30, 2010.

Back Bay NWR, currently 9,035 acres, was established in 1938 by Executive Order 7907 "* * * as a Refuge and breeding ground for migratory birds and other wildlife." Another of the refuge's primary purposes for lands acquired under the Migratory Bird Conservation Act is "* * * use as an inviolate sanctuary, or for any other management purpose, for migratory birds." The Emergency Wetlands Resources Act of 1986 also authorizes purchase of wetlands for the purpose of "* * * the conservation of the wetlands of the Nation in order to maintain the public benefits they provide and to help fulfill international obligations contained in various migratory bird treaties and conventions," using money from the Land and Water Conservation Fund. In 1939, presidential proclamation closed 4,600 acres of open bay waters within the refuge boundary to the taking of migratory birds. The refuge includes 5 miles of oceanfront beach, a 900-acre freshwater impoundment complex, numerous bay islands, bottomland mixed forests, old fields, and freshwater wetlands adjacent to Back Bay and its tributary shorelines.

Although wildlife and habitat conservation come first on the refuge, the public can enjoy excellent opportunities to observe and photograph wildlife, fish, hunt, or participate in environmental education and interpretation. Current visitor facilities are primarily located in the eastern, barrier island portion of the refuge, where annual visitation is greater than 100,000. Back Bay NWR provides scenic trails, a visitor contact station, and, with advance scheduling, group educational opportunities. Outdoor facilities are open daily, dawn to dusk.

We announce our decision and the availability of the FONSI for the final CCP for Back Bay NWR in accordance with National Environmental Policy Act (40 CFR 1506.6(b)) requirements. We completed a thorough analysis of impacts on the human environment, which we included in the draft CCP/EA. The CCP will guide us in managing and administering Back Bay NWR for the next 15 years. Alternative B, as we described in the draft CCP/EA, is the foundation for the final CCP.

Background

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each national wildlife refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing toward the mission of the National Wildlife Refuge System, consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Administration Act.

CCP Alternatives, Including Selected Alternative

Our draft CCP/EA (75 FR 15721) addressed several key issues, including ways to improve access and opportunities for public use while ensuring the restoration and protection of priority resources, the evaluation of wilderness characteristics of refuge lands, the role of cooperative farming, and the management of invasive or nuisance species on the refuge.

To address these issues and develop a plan based on the purposes for establishing the refuge, and the vision and goals we identified, three alternatives were evaluated in the EA. The alternatives have some actions in common, such as encouraging research that benefits our resource decisions, maintaining a proactive law enforcement program, protecting cultural resources, continuing to acquire land from willing sellers within our approved refuge boundary, and distributing refuge revenue sharing payments to counties.

Other actions distinguish the alternatives. Alternative A, or the "No Action Alternative," is defined by our current management activities. It serves as the base-line against which to compare the other two alternatives. Our habitat management and visitor services programs would not change under this alternative. We would continue to use the same tools and techniques, and not expand existing facilities.

Alternative B, the "Service-preferred Alternative," reflects a management emphasis on enhancing conservation of wildlife through habitat management, as well as providing additional visitor opportunities on the refuge. Some of the major strategies proposed include: Opening up the forest canopy by selectively removing loblolly pine, sweetgum, and red maple; withdrawing the 1974 wilderness designation proposal for Long Island, Green Hills, and Landing Cove (2,165 acres); developing a canoe/kayak trail on the

west side of the refuge; expanding the deer hunt; developing new hiking trails; and developing and designing a new headquarters/visitor contact station.

Alternative C features additional management that aims to restore (or mimic) natural ecosystem processes or functions to achieve refuge purposes. Alternative C focuses on using management techniques that would encourage forest growth and includes an increased focus toward the previously proposed wilderness areas. Strategies proposed include creating conditions that allow us to shift more resources from intensive management of the refuge impoundment system to the restoration of Back Bay-Currituck Sound. In addition, we propose to develop and design a new headquarters/visitor contact station that provides more office space than proposed for Alternative B; and we also plan to work with partners to provide a shuttle service (for a fee) from the new headquarters site to the barrier spit.

Comments

We solicited comments on the draft CCP/EA for Back Bay NWR from March 30 to May 1, 2010 (75 FR 15721). We received comments from 162 individuals, organizations, and State and Federal agencies on our draft plan via electronic mail, phone, and letters. All comments we received were evaluated. A summary of those comments and our responses to them is included as Appendix K in the CCP.

Selected Alternative

After considering the comments we received on our draft CCP/EA, we have selected Alternative B for implementation. Alternative B comprises the mix of actions that, in our professional judgment, works best towards achieving refuge purposes, our vision and goals, and the goals of other State and regional conservation plans. We also believe it most effectively addresses the key issues raised during the planning process. The basis of our decision is detailed in Appendix L of the CCP.

Public Availability of Documents

You can view or obtain documents as indicated under **ADDRESSES**.

Dated: November 17, 2010.

Salvatore M. Amato,

Acting Regional Director, Northeast Region, U.S. Fish and Wildlife Service, Hadley, MA 01035.

[FR Doc. 2011–97 Filed 1–6–11; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

National Park Service

[2280–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before December 18, 2010. Pursuant to sections 60.13 or 60.15 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by January 24, 2011.

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

J. Paul Loether,

Chief, National Register of Historic Places/National Historic Landmarks Program.

ARKANSAS

Desha County

Dickinson-Moore House, 707 Robert S Moore Ave, Arkansas, 10001192

CALIFORNIA

Mariposa County

El Portal Old Schoolhouse, Chapel Lane, El Portal, 10001190

Nevada County

North Star House, 12075 Old Auburn Rd, Grass Valley, 10001191

FLORIDA

Miami-Dade County

Fowey Rocks Light, (Light Stations of the United States MPS) Offshore in Straits of Florida 6.3 mi SSE of Cape Florida on Key Biscayne, Florida, 10001181

Monroe County

American Shoal Light, (Light Stations of the United States MPS) Offshore of the lower Florida Keys, 9.6 mi SW of Summerland Key, Summerland Key, 10001189

IOWA

Dubuque County

Banner Dairy Lunch Company, (Dubuque, Iowa MPS) 756 Main St, Dubuque, 10001183

LOUISIANA

Natchitoches Parish

Flora Commissary, LA HWY 120, approximately ¼ mi W of LA HWY 478, Flora, 10001194

Orleans Parish

Bohn Motor Company Automobile Dealership, 2700 S Broad, New Orleans, 10001193

MONTANA

Big Horn County

Young, Alvin, Barn and Cabin Historic District, HC 42 Box 640, Busby, 10001188

NORTH DAKOTA

Barnes County

Amphitheater and Fieldstone WPA Features at Valley City Pioneer Park, SW of the intersection between 5th St and 8th Ave NW, Valley City, 10001195

OKLAHOMA

Murray County

Travertine Nature Center, E of SHWY 177, Sulpher, 10001180

SOUTH CAROLINA

Greenville County

Greer Post Office, 106 S Main St, Greer, 10001184

VIRGINIA

Fairfax County

Panorama, 1005 Panorama Rd, Montross, 10001186

Halifax County

Town of Halifax Court House Historic District, Main St, Cemetery St, Prizery St, Edmunds Boulevard, Mary Bethune St, Cowford Rd, Maple Ave, Church St, Cary St, Halifax, 10001187

Mathews County

Donk's Theatre, 259 Buckley Hall Rd, Hudgins, 10001185

WISCONSIN

Waukesha County

Oliver, Own and Margaret, House, W 314 S 3986 SHWY 83, Genesee, 10001182

Other Actions: Request for REMOVAL has been made for the following resources:

NORTH DAKOTA

Foster County

Lincoln Building, Off US 281, Carrington, 80002912

Burleigh County

Yegen House and Yegen's Pioneer Grocery, 808–810 E Main Ave, Bismarck, 77001023

[FR Doc. 2011–65 Filed 1–6–11; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Clean Air Act

Under 28 CFR 50.7, notice is hereby given that on December 30, 2010, a proposed Consent Decree ("Consent Decree") in the matter of *United States* v. *Commonwealth of Pennsylvania, et al,* Civil Action No. 4:10–cv–02672–CCC, was lodged with the United States District Court for the Middle District of Pennsylvania.

In the complaint in this matter, the United States sought injunctive relief and civil penalties against the Pennsylvania Department of Corrections and Department of General Services (collectively, the "Commonwealth") for claims arising under the Clean Air Act in connection with the operation of four state correctional facilities located in Muncy, Bellefonte (Rockview), Somerset, and Huntingdon, PA. Under the Consent Decree, the Commonwealth will control particulate matter emissions at the facilities by either shutting down coal-fired boilers, installing air emission controls, or converting the coal-fired boilers to natural gas-fired boilers. The Commonwealth will pay a civil penalty of $300,000 for past violations. The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *United States* v. *Commonwealth of Pennsylvania, et al*, D.J. Ref. No. 90–5–2–1–09099.

The Consent Decree may be examined at the Office of the United States Attorney, Harrisburg Federal Building and Courthouse, 228 Walnut Street, Suite 200, Harrisburg, Pennsylvania, 17108–1754 and at U.S. EPA Region 3, 1650 Arch Street, Philadelphia, Pennsylvania, 19103–2029. During the public comment period, the Consent Decree may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov)* fax number (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $8.00 (25 cents per page reproduction cost) payable to the U.S. Treasury, or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–68 Filed 1–6–11; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of an Extended Benefit (EB) Period for Puerto Rico

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This notice announces a change in benefit period eligibility under the EB Program for Puerto Rico.

The following change has occurred since the publication of the last notice regarding the State's EB status:

• Puerto Rico's 13-week IUR has fallen below the 6% threshold and does not equal or exceed 120% of the average rate in the two prior years. As a result of data reported for the week ending November 27, 2010, Puerto Rico has triggered off of EB. Puerto Rico's payable period in the Federal-State Extended Benefit program will conclude December 18, 2010, and Puerto Rico will enter a mandatory 13 week "off" period.

Information for Claimants

The duration of benefits payable in the EB Program, and the terms and conditions on which they are payable, are governed by the Federal-State Extended Unemployment Compensation Act of 1970, as amended, and the operating instructions issued to the States by the U.S. Department of Labor. In the case of a State ending an EB period, the State Workforce Agency will furnish a written redetermination of benefit eligibility to each individual who was potentially eligible for EB under 20 CFR 615.13(c)(1).

Persons who wish to inquire about their rights or eligibility under the program should contact their State Workforce Agency.

FOR FURTHER INFORMATION CONTACT: Scott Gibbons, U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, 200 Constitution Avenue, NW., Frances Perkins Bldg. Room S–4231, Washington, DC 20210, telephone number (202) 693–3008 (this is not a toll-free number) or by e-mail: *gibbons.scott@dol.gov.*

Dated: December 30, 2010.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2011–101 Filed 1–6–11; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0048]

Standard on Powered Platforms for Building Maintenance; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal to extend OMB approval of the information collection requirements specified in its Standard on Powered Platforms for Building Maintenance (29 CFR 1910.66).

DATES: Comments must be submitted (postmarked, sent, or received) by March 8, 2011.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, OSHA Docket No. OSHA–2010–0048, U.S. Department of Labor, Occupational Safety and Health Administration, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., e.t.

Instructions: All submissions must include the Agency name and OSHA docket number for the Information Collection Request (ICR)(OSHA–2010–0048). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT:

Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of efforts in obtaining information (29 U.S.C. 657).

Paragraph (e)(9) of the Standard requires that employers develop and implement a written emergency action plan for each type of powered platform operation. The plan must explain the emergency procedures that workers are to follow if they encounter a disruption of the power supply, equipment failure, or other emergency. Prior to operating a powered platform, employers must notify workers how they can inform themselves about alarm systems and emergency escape routes, and emergency procedures that pertain to the building on which they will be working. Employers are to review with each worker those parts of the emergency action plan that the worker must know to ensure their protection during an emergency; these reviews must occur when the worker receives an initial assignment involving a powered platform operation and after the employer revises the emergency action plan.

According to paragraph (f)(5)(i)(C), employers must affix a load rating plate to a conspicuous location on each suspended unit that states the unit's weight and its rated load capacity. Paragraph (f)(5)(ii)(N) requires employers to mount each emergency electric operating device in a secured compartment and label the device with instructions for its use. After installing a suspension wire rope, paragraphs (f)(7)(vi) and (f)(7)(vii) mandate that employers attach a corrosion-resistant tag with specified information to one of the wire rope fastenings if the rope is to remain at one location. In addition, paragraph (f)(7)(viii) requires employers who resocket a wire rope to either stamp specified information on the original tag or put that information on a supplemental tag and attach it to the fastening.

Paragraphs (g)(2)(i) and (g)(2)(ii) require that building owners, at least annually, have a competent person: Inspect the supporting structures of their buildings; inspect and, if necessary, test the components of the powered platforms, including control systems; inspect/test components subject to wear (*e.g.*, wire ropes, bearings, gears, and governors); and certify these inspections and tests. Under paragraph (g)(2)(iii), building owners must maintain and, on request, disclose to OSHA a written certification record of these inspections/tests; this record must include the date of the inspection/test, the signature of the competent person who performed it, and the number/identifier of the building support structure and equipment inspected/tested.

Paragraph (g)(3)(i) mandates that building owners use a competent person to inspect and, if necessary, test each powered platform facility according to the manufacturer's recommendations every 30 days, or prior to use if the work cycle is less than 30 days. Under paragraph (g)(3)(ii), building owners must maintain and, on request, disclose to the Agency a written certification record of these inspections/tests; this record is to include the date of the inspection/test, the signature of the competent person who performed it, and the number/identifier of the powered platform facility inspected/tested.

According to paragraph (g)(5)(iii), building owners must use a competent person to thoroughly inspect suspension wire ropes for a number of specified conditions once a month, or before placing the wire ropes into service if the ropes are inactive for 30 days or longer. Paragraph (g)(5)(v) requires building owners to maintain and, on request, disclose to OSHA a written certification record of these monthly inspections; this record must consist of the date of the inspection, the signature of the competent person who performed it, and the number/identifier of the wire rope inspected.

Paragraph (i)(1)(ii) requires that all workers who operate working platforms be trained in the following: (A)

Recognition of, and preventive measures for, the safety hazards associated with their individual work tasks; (B) General recognition and prevention of safety hazards associated with the use of working platforms; (C) Emergency action plan procedures required in paragraph (e)(9) of this section; (D) Work procedures required in paragraph (i)(1)(iv) of this section; (E) Personal fall arrest system inspection, care, use and system performance. Paragraph (i)(1)(iii) requires that training of workers in the operation and inspection of working platforms be performed by a competent person. Paragraph (i)(1)(iv) requires that written work procedures for the operation, safe use and inspection of working platforms be provided for worker training.

Upon completion of this training, paragraph (i)(1)(v) specifies that employers must prepare a written certification that includes the identity of the worker trained, the signature of the employer or the trainer, and the date the worker completed the training. In addition, the employer must maintain a worker's training certificate for the duration of their employment and, on request, make it available to OSHA.

Emergency action plans allow employers and workers to anticipate, and effectively respond to, emergencies that may arise during powered platform operations. Affixing load rating plates to suspended units, instructions to emergency electric operating devices, and tags to wire rope fasteners prevent workplace accidents by providing information to employers and workers regarding the conditions under which they can safely operate these system components. Requiring building owners to establish and maintain written certification of inspections and testing conducted on the supporting structures of buildings, powered platform systems, and suspension wire ropes provides employers and workers with assurance that they can operate safely from the buildings using equipment that is in safe operating condition.

The training requirements increase worker safety by allowing them to develop the skills and knowledge necessary to effectively operate, use, and inspect powered platforms, recognize and prevent safety hazards associated with platform operation, respond appropriately under emergency conditions, and maintain and use their fall protection arrest system. In addition, the paperwork requirements specified by the Standard provide the most efficient means for an OSHA compliance officer to determine whether or not employers and building owners are providing the required notification and certification.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend its approval of the information collection requirements contained in the Standard on Powered Platforms for Building Maintenance (29 CFR 1910.66). The Agency is requesting to retain its current burden hour total of 135,656 hours associated with this Standard. The Agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Standard on Powered Platforms for Building Maintenance (29 CFR 1910.66).

OMB Number: 1218–0121.

Affected Public: Business or other for-profits.

Number of Respondents: 900.

Frequency: On occasion; Initially, Monthly, Annually.

Average Time Per Response: Varies from 2 minutes (.03 hour) to disclose certification records to 4 hours to inspect/test both a powered platform facility and its suspension wire ropes, and to prepare the certification record.

Total Burden Hours Requested: 135,656.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on this Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov*, which is the Federal eRulemaking Portal; (2) by facsimile (FAX); or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for the ICR (Docket No. OSHA–2010–0048). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (*see* the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov*. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and date of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.*, copyrighted material) is not publicly available to read or download through this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available through the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, PhD, MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 4–2010 (75 FR 55355).

Signed at Washington, DC, on January 3, 2011.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011–87 Filed 1–6–11; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Privacy Act System of Records Notice (11–001)

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of Privacy Act system of records.

SUMMARY: Each Federal agency is required by the Privacy Act of 1974 to publish a description of the systems of records it maintains containing personal information when a system is substantially revised, deleted, or created. In this notice, NASA provides the required information for a new Agency-wide Privacy Act system of records generated in the process of complying with NASA's anti-harassment procedural requirements governing the reporting, fact-finding and resolution of allegations of harassment reported to NASA by its employees and contractors. This new system of records will assist NASA in fulfilling its obligations pursuant to the Supreme Court cases of *Burlington Industries* v. *Ellerth,* 524 U.S. 742 (1998), and *Faragher* v. *City of Boca Raton,* 524 U.S. 775 (1998): (1) To prevent harassment before it becomes severe or pervasive; (2) to conduct a prompt, thorough, and impartial investigation into allegations of harassing conduct; and (3) to take immediate and appropriate corrective action when the Agency determines that harassing conduct has occurred.

DATES: Submit comments on or before 60 calendar days from the date of this publication.

ADDRESSES: Patti F. Stockman, NASA Privacy Act Officer, Office of the Chief Information Officer, NASA Headquarters, 300 E Street, SW., Washington, DC 20546–0001, 202–358–4787, *NASA–PAOfficer@nasa.gov*.

FOR FURTHER INFORMATION CONTACT: Patti F. Stockman, NASA Privacy Act Officer, 202–358–4787, *NASA–PAOfficer@nasa.gov*.

SUPPLEMENTARY INFORMATION: None.

SYSTEM NUMBER:

NASA 10HRCF

SYSTEM NAME:

Harassment Report Case Files

SECURITY CLASSIFICATION:

None

SYSTEM LOCATION:

Locations 1 through 11 as set forth in Appendix A.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains information on individuals who have reported harassing conduct by or against NASA civil servants. This includes but is not limited to current and former NASA employees and contractors and others who have reported allegations of harassment by or against NASA civil servants. It also includes information on witnesses and others contacted as part of the fact-finding process.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains records including names, position, and contact information of individuals involved in reports or allegations of harassment, as well as facts gathered about alleged harassment incidents. It also includes records such as fact-finding reports, findings and corrective actions, if necessary, and close out letters.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 2473, 44 U.S.C. 3101, 29 U.S.C. 621 et. seq.; 29 U.S.C. 791 et. seq.; 42 U.S.C. 2000e–16 et seq.; 42 U.S.C. 12101; Exec. Order No. 11478, 34 FR 12985; Exec. Order No. 13087, 63 FR 30097; Exec. Order No. 13152, 65 FR 26115.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

Any disclosures of information will be compatible with the purpose for which the Agency collected the information. Records from this system may be disclosed, as necessary:

(1) To any source from which additional information is requested in the course of processing a report of harassment made pursuant to NASA policy;

(2) To contractors conducting the fact-finding inquiry on behalf of NASA;

(3) To an authorized grievance official, complaints examiner, administrative judge, contract investigator, arbitrator, or duly authorized official for use in investigation, litigation, or settlement of a non-harassment grievance, complaint, or appeal filed by an employee;

(4) Under NASA standard routine uses 1 through 6 as set forth in Appendix B.

POLICIES AND PRACTICES FOR STORING, RETRIEVING ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are maintained in paper file folders and on electronic media.

RETRIEVABILITY:

These records may be retrieved by the name of the alleged harassee or by the name of the alleged harasser.

SAFEGUARDS:

Records are maintained in locked file cabinets or in secured rooms with access limited to those whose official duties require access. Electronic data are maintained in encrypted files on secure servers with limited access to computerized records through use of access codes and entry logs, to only those whose official duties require access.

RETENTION AND DISPOSAL:

These records will be maintained for four years after the report of harassment is closed, in accordance with the disposition authorization, when approved under NARA N1–255–11–01, that will be incorporated in the NPR 1441.1 NASA Records Retention Schedules as Schedule 3, Item 53.5.

SYSTEM MANAGER AND ADDRESS:

System Manager: Agency Anti-Harassment Coordinator, NASA Headquarters, 300 E Street, SW., Mail Stop 4W39, Washington, DC 20546–0001.

Subsystem Managers: Center Anti-Harassment Coordinators at each of the locations 1 through 11 as set forth in Appendix A.

NOTIFICATION PROCEDURE:

Information may be obtained from the cognizant system or subsystem manager of locations listed above where the requested records are held.

RECORD ACCESS PROCEDURES:

Individuals who wish to gain access to their records should submit their request in writing to the System Manager or Subsystem Manager at locations listed above.

CONTESTING RECORD PROCEDURES:

The NASA regulations for access to records and for contesting contents and appealing initial determinations by the individual concerned appear in 14 CFR Part 1212.

RECORD SOURCE CATEGORIES:

The information is obtained from current and former employees, current and former contractor employees, Fact-Finders, Agency Anti-Harassment Coordinator, and Center Anti-Harassment Coordinators.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Linda Y. Cureton,

NASA Chief Information Officer.

Appendix A— Location Numbers and Mailing Addresses of NASA Installations at Which Records Are Located

Location 1

NASA Headquarters, National Aeronautics and Space Administration Washington, DC 20546–0001

Location 2

Ames Research Center, National Aeronautics and Space Administration, Moffett Field, CA 94035–1000

Location 3

Dryden Flight Research Center, National Aeronautics and Space Administration, PO Box 273, Edwards, CA 93523–0273

Location 4

Goddard Space Flight Center, National Aeronautics and Space Administration, Greenbelt, MD 20771–0001

Location 5

Lyndon B. Johnson Space Center, National Aeronautics and Space Administration, Houston, TX 77058–3696

Location 6

John F. Kennedy Space Center, National Aeronautics and Space Administration, Kennedy Space Center, FL 32899–0001

Location 7

Langley Research Center, National Aeronautics and Space Administration, Hampton, VA 23681–2199

Location 8

John H. Glenn Research Center at Lewis Field, National Aeronautics and Space Administration, 21000 Brookpark Road, Cleveland, OH 44135–3191

Location 9

George C. Marshall Space Flight Center, National Aeronautics and Space Administration, Marshall Space Flight Center, AL 35812–0001

Location 10

John C. Stennis Space Center, National Aeronautics and Space Administration, Stennis Space Center, MS 39529–6000

Location 11

NASA Shared Services Center (NSSC), Building 5100, Stennis Space Center, MS 39529–6000

Appendix B—Standard Routine Uses—NASA

The following routine uses of information contained in Systems of Records (SORs), subject to the Privacy Act of 1974, are standard for many NASA systems. They are cited by reference in the paragraph "Routine uses of records maintained in the system, including categories of users and the purpose of such uses" of the Federal Register Notice on those systems to which they apply.

Standard Routine Use No. 1—LAW ENFORCEMENT:

In the event this SOR indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the SOR may be referred, as a routine use, to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

Standard Routine Use No. 2—DISCLOSURE WHEN REQUESTING INFORMATION:

A record from this SOR may be disclosed as a "routine use" to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

Standard Routine Use No. 3—DISCLOSURE OF REQUESTED INFORMATION:

A record from this SOR may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

Standard Routine Use No. 4—DISCLOSURE TO THE DEPARTMENT OF JUSTICE FOR USE IN LITIGATION:

A record from this SOR may be disclosed to the Department of Justice when (a) the Agency, or any component thereof; or (b) any employee of the Agency in his or her official capacity; or (c) any employee of the Agency in his or her individual capacity where the Department of Justice or the Agency has agreed to represent the employee; or (d) the United States, where the Agency determines that litigation is likely to affect the Agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or the Agency is deemed by the Agency to be relevant and necessary to the litigation provided, however, that in each case it has been determined that the disclosure is compatible with the purpose for which the records were collected.

Standard Routine Use 5—ROUTINE USE FOR AGENCY DISCLOSURE IN LITIGATION:

It shall be a routine use of the records in this SOR to disclose them in a proceeding before a court or adjudicative body before which the agency is authorized to appear, when: (a) The Agency, or any component thereof; or (b) any employee of the Agency in his or her official capacity; or (c) any employee of the Agency in his or her individual capacity where the Agency has agreed to represent the employee; or (d) the United States, where the Agency determines that litigation is likely to affect the Agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Agency is deemed to be relevant and necessary to the litigation, provided, however, that in each case, the Agency has determined that the disclosure is compatible with the purpose for which the records were collected.

Standard Routine Use No. 6—SUSPECTED OR CONFIRMED CONFIDENTIALITY COMPROMISE:

A record from this SOR may be disclosed to appropriate agencies, entities, and persons when (1) NASA suspects or has confirmed that the security or confidentiality of information in the SOR has been compromised; (2) NASA has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by NASA or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably

necessary to assist in connection with NASA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

[FR Doc. 2011–31 Filed 1–6–11; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL LABOR RELATIONS BOARD

Sunshine Act Meetings: January 2011

TIME AND DATES: All meetings are held at 2:30 p.m.

Tuesday, January 4; Wednesday, January 5; Thursday, January 6; Friday, January 7; Tuesday, January 11; Wednesday, January 12; Thursday, January 13; Friday, January 14; Tuesday, January 18; Wednesday, January 19; Thursday, January 20; Friday, January 21; Tuesday, January 25; Wednesday, January 26; Thursday, January 27; Friday, January 28.

PLACE: Board Agenda Room, No. 11820, 1099 14th St., NW., Washington DC 20570.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Pursuant to § 102.139(a) of the Board's Rules and Regulations, the Board or a panel thereof will consider "the issuance of a subpoena, the Board's participation in a civil action or proceeding or an arbitration, or the initiation, conduct, or disposition * * * of particular representation or unfair labor practice proceedings under section 8, 9, or 10 of the [National Labor Relations] Act, or any court proceedings collateral or ancillary thereto." See also 5 U.S.C. 552b(c)(10).

CONTACT PERSON FOR MORE INFORMATION: Lester A. Heltzer, Executive Secretary, (202) 273–1067.

Dated: January 5, 2011.

Lester A. Heltzer,

Executive Secretary.

[FR Doc. 2011–260 Filed 1–5–11; 4:15 pm]

BILLING CODE 7545–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–528, 50–529, 50–530; NRC–2009–0012]

Arizona Public Service Company, Palo Verde Nuclear Generating Station; Notice of Availability of the Final Supplement 43 to the Generic Environmental Impact Statement for License Renewal of Nuclear Plants

Notice is hereby given that the U.S. Nuclear Regulatory Commission (NRC) has published a final plant-specific supplement to the *Generic Environmental Impact Statement for License Renewal of Nuclear Plants* (GEIS), NUREG–1437, regarding the renewal of operating licenses NPF–41, NPF–51 and NPF–74 for an additional 20 years of operation for the Palo Verde Nuclear Generating Station (PVNGS). Possible alternatives to the proposed action (license renewal) include no action and reasonable alternative energy sources.

As discussed in Section 9.4 of the final supplement, the staff determined that the adverse environmental impacts of license renewal for PVNGS are not so great that preserving the option of license renewal for energy planning decision makers would be unreasonable. This recommendation is based on: (1) The analysis and findings in the GEIS; (2) information provided in the environmental report (ER) submitted by Arizona Public Service Company; (3) consultation with Federal, State, and local agencies; (4) a review of pertinent documents and reports; and (5) consideration of public comments received during scoping and on the draft SEIS.

The final Supplement 43 to the GEIS is publicly available at the NRC Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, or from the NRC's Agencywide Documents Access and Management System (ADAMS). The ADAMS Public Electronic Reading Room is accessible at *http://www.nrc.gov/reading-rm/adams.html.* The accession number for the final Supplement 43 to the GEIS is ML103560149. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR reference staff by telephone at (800) 397–4209 or (301) 415–4737, or by e-mail at *pdr@nrc.gov.* In addition, the Litchfield Park Branch Library, 101 West Wigwam Boulevard, Litchfield Park, AZ 85340, has agreed to make the final supplement available for public inspection.

FOR FURTHER INFORMATION CONTACT: Mr. David Drucker, Program Operations Branch, Division of License Renewal, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Mail Stop O–11F1, Washington, DC 20555–0001. Mr. Drucker may be contacted by telephone at (800) 368–5642, extension 6223, or via e-mail at *david.drucker@nrc.gov.*

Dated at Rockville, Maryland, this 3rd day of January 2011.

For the Nuclear Regulatory Commission.

Trent Wertz,

Chief, Program Operations Branch, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2011–108 Filed 1–6–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–341; NRC–2010–0388]

Detroit Edison Company, FERMI 2; Exemption

1.0 Background

Detroit Edison Company (DECo) (the licensee) is the holder of Facility Operating License No. NFP–43 which authorizes operation of the Fermi 2. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect. The facility consists of a boiling water reactor located in Monroe County in Michigan.

2.0 Request/Action

Title 10 of the *Code of Federal Regulations* (10 CFR), Part 50, Appendix E, Section IV.F.2.b requires that "Each licensee at each site shall conduct an exercise of its onsite emergency plan every 2 years." By letter dated August 3, 2010 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML102230442), the licensee requested a one-time exemption from this requirement that would have allowed the licensee to not conduct the onsite portion of a biennial emergency preparedness (EP) exercise in 2010. Requests for additional information (RAIs) were sent to the licensee on September 13, 2010 (ADAMS Accession No. ML102580355), and a teleconference was held with the licensee on September 17, 2010, to discuss the RAIs. By letter dated October 22, 2010 (ADAMS Accession No. ML102950490), the licensee responded to the RAIs and amended their request to include only a one-time

schedular exemption to postpone the onsite portion of the biennial EP exercise until calendar year (CY) 2011. As a result of the licensee's responses to first set of RAIs, a second set of RAIs were sent to the licensee on October 29, 2010 (ADAMS Accession No. ML103050328). A telephone call was conducted with the licensee on November 4, 2010, to discuss these additional RAIs. The licensee responded to the second set of RAIs by letter dated November 15, 2010 (ADAMS Accession No. ML103200126).

The licensee's original request for an exemption stated that a tornado swept across the Fermi 2 property on June 6, 2010, and that the resulting damage led to an Alert declaration and the activation of the licensee's Emergency Response Organization (ERO). Due to the tornado event, the licensee chose to cancel its scheduled biennial EP exercise on June 8, 2010. In the original request, the licensee asked to be given credit for their scheduled 2010 biennial EP exercise based upon the Alert declaration and subsequent response to the June 6, 2010, tornado event. In the licensee's letter in response to the first set of RAIs, the licensee states that: "Rescheduling the cancelled exercise in calendar year 2010 is not considered due to the unavailability of resources necessary to prepare for and conduct an NRC-evaluated exercise. DECo resources since the cancellation of the exercise were devoted to safely planning and preparing for the fall refueling outage." The licensee's original request stated that it did participate in a limited scope biennial EP exercise utilizing partial onsite participation and full participation by state and local response organizations on June 8, 2010. Participation by state and local response organizations was evaluated by the Federal Emergency Management Agency (FEMA) and therefore met the biennial exercise requirement for these offsite agencies.

In summary, as a result of the impact of the combined need to recover from the tornado damage and support a scheduled refueling outage, the licensee requested, in response to the staff RAIs, an exemption that would allow rescheduling the onsite portion of the exercise from CY 2010 until CY 2011.

3.0 Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50, Appendix E, when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) special circumstances are present.

Authorized by Law

This exemption would allow the licensee to accommodate these impacts upon its resources by postponing the onsite portion of the exercise from the previously scheduled date during CY 2010 until CY 2011.

As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR Part 50, Appendix E. The NRC staff has determined that granting of the licensee's proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

No Undue Risk to Public Health and Safety

The underlying purpose of 10 CFR part 50, Appendix E, Section IV.F.2.b requiring licensees to conduct a biennial EP exercise is to ensure that ERO personnel are familiar with their duties and to test the adequacy of emergency plans. In addition, 10 CFR part 50, Appendix E, Section IV.F.2.b also requires licensees to maintain adequate emergency response capabilities during the intervals between biennial EP exercises by conducting drills to exercise the principal functional areas of emergency response. In order to accommodate the scheduling of full participation exercises, the NRC has allowed licensees to schedule the exercises at any time during the calendar biennium. Conducting the Fermi 2 full-participation exercise in CY 2011, rather than CY 2010, places the exercise outside of the required biennium. Since the last biennial EP exercise on May 20, 2008, the licensee has conducted 20 training drills that collectively exercised the principal functional areas of emergency response, including management, coordination of emergency response, accident assessment, protective action decision making, and plant system repair and corrective actions. These drills, collectively, involved all onsite emergency response facilities and many of the drills included participation by offsite response organizations. In addition, at the request of FEMA, the licensee supported the State and local authorities with the offsite portion of the biennial EP exercise on June 8, 2010, thereby facilitating the FEMA evaluation of the State and local authorities. The NRC staff considers the intent of this requirement is met by having conducted these series of training drills.

Based on the above, no new accident precursors are created by allowing the licensee to postpone the onsite portion of the exercise from the previously scheduled date of June 8, 2010, to CY 2011. Thus, the probability and consequences of postulated accidents are not increased. Therefore, there is no undue risk to public health and safety.

Consistent With Common Defense and Security

The proposed exemption would allow rescheduling of the onsite portion of the biennial EP exercise from the previously scheduled date of June 8, 2010, to CY 2011. This change to the EP exercise schedule has no relation to security issues. Therefore, the common defense and security is not impacted by this exemption.

Special Circumstances

In order to grant exemptions in accordance with 10 CFR 50.12, special circumstances must be present. Special circumstances per 10 CFR 50.12 that apply to this exemption request are 10 CFR 50.12(a)(2)(ii) and (v). Special circumstances, per 10 CFR 50.12(a)(2)(ii), are present when: "Application of the regulation in the particular circumstances would not serve the underlying purpose of the rule or is not necessary to achieve the underlying purpose of the rule." Section IV.F.2.b of 10 CFR Part 50, Appendix E requires licensees at each site to conduct an exercise of onsite emergency plans biennially with full-participation by each offsite authority having a role under the plan. The underlying purposes of 10 CFR part 50, Appendix E, Section IV.F.2.b requiring licensees to conduct a biennial EP exercise is to ensure that ERO personnel are familiar with their duties and to test the adequacy of emergency plans. Since the licensee has conducted 20 training drills exercising the principle functional areas of emergency response since the last evaluated biennial EP exercise, has activated all onsite emergency response facilities during those drills, and has supported the FEMA evaluation of the State and local authorities, the NRC staff considers that these measures are adequate to maintain an acceptable level of emergency preparedness during this period, satisfying the underlying purpose of the rule.

Under 10 CFR 50.12(a)(2)(v), special circumstances are present whenever the exemption would provide only temporary relief from the applicable regulation and the licensee or applicant has made good faith efforts to comply

with the regulation. Due to the activation of ERO personnel as a result of the tornado two days prior to June 8, 2010 biennial exercise, the 20 training drills conducted since the last evaluated biennial EP exercise, and the licensee's support of the FEMA evaluation of the State and local authorities during the June 8, 2010 exercise, the NRC staff considers the licensee to have made good faith efforts to comply with the regulation. Also, the requested exemption to conduct the onsite EP exercise in CY 2011 instead of CY 2010 would grant only temporary relief from the applicable regulation. Since the underlying purpose of 10 CFR part 50, Appendix E, Section IV.F.2.b is achieved, the licensee has made a good faith effort to comply with the regulation, and the exemption would grant only temporary relief from the applicable regulation, the special circumstances required by 10 CFR 50.12(a)(2)(ii and v) exist for the granting of an exemption.

4.0 Conclusion

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, is consistent with the common defense and security, and special circumstances are present. Therefore, the Commission, hereby grants DECo an exemption from the requirements of 10 CFR Part 50, Appendix E, Section IV.F.2.b to conduct the onsite portion of the Fermi 2 biennial EP exercise required for CY 2010, permitting that part of the exercise to be conducted in coordination with NRC Region III and Fermi 2 plant schedule as soon as reasonably achievable in CY 2011.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not have a significant effect on the quality of the human environment (75 FR 81316).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 27th day of December 2010.

For the Nuclear Regulatory Commission.

Allen. G. Howe,

Acting Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2011–113 Filed 1–6–11; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2011–18 and CP2011–57; Order No. 635]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request to add Priority Mail Contract 35 to the competitive product list. This notice addresses procedural steps associated with this filing.

DATES: *Comments are due:* January 12, 2011.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Commenters who cannot submit their views electronically should contact the person identified in **FOR FURTHER INFORMATION CONTACT** by telephone for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, *stephen.sharfman@prc.gov* or 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 35 to the competitive product list.[1] Priority Mail contracts enable the Postal Service to provide Priority Mail service to an individual customer at customized rates.[2] The Postal Service asserts that Priority Mail Contract 35 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). Request at 1. The Request has been assigned Docket No. MC2011–18.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.,* Attachment B. The instant contract has been assigned Docket No. CP2011–57.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 09–6, authorizing certain Priority Mail contracts, and a certification of the Governors' vote;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list that would add Priority Mail Contract 35 under Domestic Negotiated Service Agreements;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract, customer-identifying information, and related financial information under seal.

In the Statement of Supporting Justification, Josen Punnoose, Manager, Shipping Support (A), Shipping Services, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to covering institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.,* Attachment D at 1. Mr. Punnoose contends that there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.,* Attachment B. The contract is scheduled to become effective 1 business day after the Commission issues all necessary regulatory approvals. *Id.* at 2. The contract will expire 3 years from the effective date unless, among other things, either party terminates the agreement upon 30 days' written notice to the other party. *Id.* at 2–3. The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a). *Id.,* Attachment D.

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.,* Attachment F. It maintains that redacted portions of the contract, customer-identifying information, and related financial information should remain confidential. *Id.* at 2–3. This information includes the price structure,

[1] Request of the United States Postal Service to Add Priority Mail Contract 35 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, December 30, 2010 (Request).

[2] Decision of the Governors of the United States Postal Service on Establishment of Rates and Classes Not of General Applicability for Priority Mail Contract Group, Docket No. MC2009–25, issued April 27, 2009, at 1 (Governors' Decision No. 09–6).

underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2011–18 and CP2011–57 to consider the Request pertaining to the proposed Priority Mail Contract 35 product and the related contract, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than January 12, 2011. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Paul L. Harrington to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2011–18 and CP2011–57 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Paul L. Harrington is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than January 12, 2011.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2011–129 Filed 1–6–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2011–17 and CP2011–56; Order No. 634]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request to add Priority Mail Contract 34 to the competitive product list. This notice addresses procedural steps associated with this filing.

DATES: *Comments are due:* January 12, 2011.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Commenters who cannot submit their views electronically should contact the person identified in **FOR FURTHER INFORMATION CONTACT** by telephone for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, *stephen.sharfman@prc.gov* or 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 34 to the competitive product list.[1] Priority Mail contracts enable the Postal Service to provide Priority Mail service to an individual customer at customized rates.[2] The Postal Service asserts that Priority Mail Contract 34 is a competitive product "not of general applicability" within the meaning of 39 U.S.C. 3632(b)(3). Request at 1. The Request has been assigned Docket No. MC2011–17.

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.,* Attachment B. The instant contract has been assigned Docket No. CP2011–56.

Request. To support its Request, the Postal Service filed six attachments as follows:

- Attachment A—a redacted copy of Governors' Decision No. 09–6, authorizing certain Priority Mail contracts, and a certification of the Governors' vote;
- Attachment B—a redacted copy of the contract;
- Attachment C—proposed changes to the Mail Classification Schedule competitive product list that would add Priority Mail Contract 34 under Domestic Negotiated Service Agreements;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the contract, customer-identifying information, and related financial information under seal.

In the Statement of Supporting Justification, Josen Punnoose, Manager, Shipping Support (A), Shipping Services, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to covering institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.,* Attachment D at 1. Mr. Punnoose contends there will be no issue of market dominant products subsidizing competitive products as a result of this contract. *Id.*

Related contract. The Postal Service included a redacted version of the related contract with the Request. *Id.,* Attachment B. The contract is scheduled to become effective 1 business day after the Commission issues all necessary regulatory approvals. *Id.,* at 2. The contract will expire 3 years from the effective date unless, among other things, either party terminates the agreement upon 30 days' written notice to the other party. *Id.* at 3. The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a). *Id.,* Attachment D.

The Postal Service filed much of the supporting materials, including the related contract, under seal. *Id.* Attachment F. It maintains that the redacted portions of the contract, customer-identifying information, and related financial information should remain confidential. *Id.* at 2–3. This information includes the price structure, underlying costs and assumptions, pricing formulas, information relevant to the customer's mailing profile, and cost coverage projections. *Id.* The Postal Service asks the Commission to protect customer-identifying information from public disclosure indefinitely. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2011–17 and CP2011–56 to consider the Request pertaining to the proposed Priority Mail Contract 34 product and the related contract, respectively.

[1] Request of the United States Postal Service to Add Priority Mail Contract 34 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, December 30, 2010 (Request).

[2] Decision of the Governors of the United States Postal Service on Establishment of Rates and Classes Not of General Applicability for Priority Mail Contract Group, April 27, 2009, at 1 (Governors' Decision No. 09–6).

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than January 12, 2011. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Paul L. Harrington to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2011–17 and CP2011–56 for consideration of the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Paul L. Harrington is appointed to serve as officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than January 12, 2011.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2011–95 Filed 1–6–11; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63628; File No. SR–NASDAQ–2010–154]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change by the NASDAQ Stock Market LLC To Enhance the Investor Support Program

January 3, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 21, 2010, The NASDAQ Stock Market LLC ("NASDAQ" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ proposes changes to the fee provisions of Rule 7014 (Investor Support Program) to enhance the Investor Support Program in respect of: Certain assumed Baseline Participation Ratio values for firms that did not add liquidity in August 2010; the addition of liquidity through Indirect Order Flow; liquidity executed at or above $1; and a certification provision.

The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com,* at NASDAQ's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASDAQ included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NASDAQ has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing changes to the fee provisions of Rule 7014 to enhance the Investor Support Program in respect of: Certain assumed Baseline Participation Ratio values for firms that did not add liquidity in August 2010; the addition of liquidity through Indirect Order Flow; liquidity executed at or above $1; and a certification provision.

The Exchange established an Investor Support Program ("ISP") that enables NASDAQ members to earn a monthly fee credit for providing additional liquidity to NASDAQ and increasing the NASDAQ-traded volume of what are generally considered to be retail and institutional investor orders in exchange-traded securities ("targeted liquidity").[3] The goal of the ISP is to incentivize members to provide such targeted liquidity to the NASDAQ Market Center.[4] The Exchange noted in the ISP Filing that maintaining and increasing the proportion of orders in exchange-listed securities executed on a registered exchange (rather than relying on any of the available off-exchange execution methods) would help raise investors' confidence in the fairness of their transactions and would benefit all investors by deepening NASDAQ's liquidity pool, supporting the quality of price discovery, promoting market transparency and improving investor protection.

The Exchange now proposes several adjustments to the Investor Support Program. The primary objective in making these adjustments is to moderate the ability of members (firms), on a prospective basis, from gaining ISP fee credits without effectively adding targeted liquidity to NASDAQ. This proposal clearly furthers the ISP goal of incentivizing members to provide targeted liquidity to the Exchange.

First, the ISP generally compares a member's Participation Ratio for the current month to the same member's Participation Ratio in August 2010 (known as the "Baseline Participation Ratio").[5] This ratio is determined by

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] For a detailed description of the Investor Support Program, *see* Securities Exchange Act Release No. 63270 (November 8, 2010), 75 FR 69489 (November 12, 2010) (NASDAQ–2010–141) (notice of filing and immediate effectiveness)(the "ISP Filing"). *See also* Securities Exchange Act Release No. 76505 (December 2, 2010), 75 FR 76505 (December 8, 2010) (NASDAQ–2010–153)(notice of filing and immediate effectiveness regarding exclusion of partial trading days from certain ISP calculations).

[4] The Commission has recently expressed its concern that a significant percentage of the orders of individual investors are executed at over the counter ("OTC") markets, that is, at off-exchange markets; and that a significant percentage of the orders of institutional investors are executed in dark pools. Securities Exchange Act Release No. 61358 (January 14, 2010), 75 FR 3594 (January 21, 2010) (Concept Release on Equity Market Structure, "Concept Release"). In the Concept Release, the Commission has recognized the strong policy preference under the Act in favor of price transparency and displayed markets. The Commission published the Concept Release to invite public comment on a wide range of market structure issues, including high frequency trading and un-displayed, or "dark," liquidity. *See also* Mary L. Schapiro, *Strengthening Our Equity Market Structure* (Speech at the Economic Club of New York, Sept. 7, 2010) ("Schapiro Speech," available on the Commission Web site)(comments of Commission Chairman on what she viewed as a troubling trend of reduced participation in the equity markets by individual investors, and that nearly 30 percent of volume in U.S.-listed equities is executed in venues that do not display their liquidity or make it generally available to the public).

[5] The term "Participation Ratio" is defined as: For a given member in a given month, the ratio of (i) the number of shares of liquidity provided in orders entered by the member through any of its NASDAQ ports and executed in the NASDAQ Market Center during such month to (ii) the consolidated volume of shares of System Securities in executed orders

Continued

measuring the number of shares in liquidity-providing orders entered by the member (through any NASDAQ port) and executed on NASDAQ and dividing this number by the consolidated (across all trading venues) share volume of System Securities [6] traded in the given month.[7]

The Exchange recognizes that some current members may not be able to establish a Baseline Participation Ratio for August 2010 (*e.g.,* they did not add liquidity in August, or were not members). For such members, the Exchange proposes to add a provision that assumes a specified value in the Participation Ratio for August 2010. Specifically, the Exchange proposes new language in subsection (d)(2) stating that in calculating the August 2010 Participation Ratio, if the result is zero (no liquidity was added), the Baseline Participation Ratio shall be deemed to be 0.485% (when rounded to three decimal places [8]), which corresponds to an average daily volume ("adv") of 35 million shares in August 2010 (the "deemed ratio").[9] The Exchange believes that 35 million adv is reasonable in light of the daily trading volumes in the competitive equity trading market. The Exchange believes further that the deemed ratio (which would be uniformly applicable to all members that did not contribute liquidity in August) is fair and equitable in that it should minimize such members gaining an advantage over members that contributed liquidity in August, and would not tend to unfairly exclude members adding targeted liquidity to the Exchange from the ISP.

Second, the Baseline Participation Ratio now captures the number of shares of liquidity provided in orders that are entered by the member directly through any of its NASDAQ ports and executed in the NASDAQ Market Center in August 2010. A member might have provided liquidity to NASDAQ, however, through means other than directly through its own NASDAQ ports (*e.g.,* indirectly thorough other members). The Exchange proposes an amendment to capture this indirect liquidity (indirect order flow) when establishing a member's Participation Ratio for the month of August 2010. Specifically, the Exchange proposes new language in subsection (d)(2) stating that in calculating the August 2010 Participation Ratio, the numerator shall be increased by the amount (if any) of the member's August 2010 Indirect Order Flow.

Indirect Order Flow is defined in new subsection (d)(5), for purposes of the rule, as the number of shares of liquidity provided in orders entered into the NASDAQ Market Center at the member's direction by another member with minimal substantive intermediation by such other member and executed in the NASDAQ Market Center during such month. NASDAQ will assess whether a member entering orders provided substantive intermediation to another member based on how much discretion the entering member had in selecting such key order attributes as symbol, price, size and time in force.

The Exchange believes that including Indirect Order Flow when calculating the August 2010 ratio should discourage (and properly account for) members simply changing how, or through whom (*e.g.,* via aggregation) they send liquidity to the Exchange to gain ISP fee payment without effectively increasing the amount of targeted liquidity sent to the Exchange. This proposal, which is equally applicable to all, is directly conducive to the goal of adding new liquidity to the Exchange. As such, the Indirect Order Flow proposal is fair and equitable to all members. Moreover, the Exchange believes that it is decidedly non-discriminatory because it promotes accurate accounting of flow from all sources, thus minimizing the ability of any particular group of members from gaining an advantage over others.[10]

Third, to determine the amount of the ISP credit pursuant to the program, NASDAQ would multiply $0.0003 by the lower of: The number of shares of displayed liquidity provided in orders entered by the member thorough its ISP-designated ports and executed in the NASDAQ Market Center during the given month; or the amount of Added Liquidity [11] for the given month. The established goal of the ISP is to attract certain targeted retail and institution liquidity. The Exchange believes that this type of retail and institutional liquidity would generally be executed at or above $1. The Exchange therefore proposes to amend the definition of shares of displayed liquidity in subsection (b)(1) to clarify that such liquidity must be executed at a price at or above $1 in the NASDAQ Market Center in order to qualify for the ISP.

Fourth, the Exchange adds a methodology by which members can demonstrate their compliance with the requirements of Rule 7014 and the ISP. The Exchange proposes to add new subsection (e) to state that a member will certify to the reasonable satisfaction of the Exchange its Baseline Participation Ratio and its compliance with any other sections or requirements of this Rule if requested by NASDAQ. The Exchange limits such certification, which would be applicable to all program participants, to not more often that once a month during a member's participation in the ISP. The Exchange believes that the certification provision would particularly help to ensure that all ISP participants may participate in the program on an equal, verifiable basis.

2. Statutory Basis

NASDAQ believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[12] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[13] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or

reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during such month. Rule 7014(d)(4). Using the consolidated volume language of subsection (d)(4)(ii), the term "Consolidated Volume" is defined as the consolidated volume of shares of System Securities in executed orders reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during such month. Rule 7014(d)(5). The term Consolidated Volume is substituted for current consolidated volume language throughout the rule.

[6] The term "System Securities" is defined as all securities listed on NASDAQ and all securities subject to the Consolidated Tape Association Plan and the Consolidated Quotation Plan. Rule 4751(b).

[7] *See* Proposed Rule 7014(d)(2).

[8] The Exchange notes that while the Baseline Participation Ratio is rounded to three decimal places in the rule for ease of notation, for ISP billing purposes the Baseline Participation Ratio will not be rounded in this manner.

[9] The .485% Baseline Participation Ratio is calculated as follows:

(22 * 35 million shares)/(August consolidated volume * 22). There were 22 trading days in the month of August 2010. The consolidated volume for August 2010 was 165.846 billion (rounded).

[10] The Exchange notes that the Indirect Order Flow proposal is not discriminatory against anyone, but to the contrary affords the Exchange a clearer picture of how all ISP participants provided flow in August. The Exchange notes further that while the Baseline Participation Ratio by definition always refers to August 2010, Indirect Order Flow was not applied during the ISP's initial months of operation (November and December) and will be applied prospectively.

[11] The term "Added Liquidity" is defined as: For a given member in a given month, the number of shares calculated by (i) subtracting from such member's Participation Ratio for that month the member's Baseline Participation Ratio, and then (ii) multiplying the resulting difference by the average daily consolidated volume of shares of System Securities in executed orders reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during such month; provided that if the result is a negative number, the Added Liquidity amount shall be deemed zero. Rule 7014(d)(1). The term "System Securities" is defined as: All securities listed on NASDAQ and all securities subject to the Consolidated Tape Association Plan and the Consolidated Quotation Plan. Rule 4751(b).

[12] 15 U.S.C. 78f.

[13] 15 U.S.C. 78f(b)(4) and (5).

system which NASDAQ operates or controls, and it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest.

The Investor Support Program encourages members to add targeted liquidity that is executed in the NASDAQ Market Center. The rule change enhances the Investor Support Program by proposing minor changes regarding certain assumed Participation Rate values for firms that did not add liquidity in August 2010; the addition of liquidity through Indirect Order Flow; liquidity executed at or above $1; and a certification provision. The primary objective in making these enhancements to the Investor Support Program is to minimize the ability of members (firms), on a prospective basis, from gaining ISP fee credits while effectively adding little or no targeted liquidity to NASDAQ. The rule change proposals "are not designed to permit unfair discrimination" [14] but, rather, are intended to promote submission of liquidity-providing orders to NASDAQ, which would benefit all NASDAQ members and all investors. Likewise, the program is consistent with the Act's requirement "for the equitable allocation of reasonable dues, fees, and other charges." [15] As explained in the immediately preceding paragraphs, the proposals enhance the goal of the ISP. Members who choose to increase the volume of ISP-eligible liquidity-providing orders that they submit to NASDAQ would be benefitting all investors, and therefore an additional credit, as contemplated in the proposed enhanced program, is equitable. Finally, NASDAQ notes that the intense competition among several national securities exchanges and numerous OTC venues effectively guarantees that fees and credits for the execution of trades in NMS securities remain equitable and are not unfairly discriminatory.[16]

B. Self-Regulatory Organization's Statement on Burden on Competition

NASDAQ does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[17] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form *(http://www.sec.gov/rules/sro.shtml);* or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2010–154 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2010–154. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2010–154 and should be submitted on or before January 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–90 Filed 1–6–11; 8:45 am]

BILLING CODE 8011–01–P

[14] *See* Section 6(b)(5) of the Act, 15 U.S.C. 78f(b)(5).

[15] *See* Section 6(b)(4) of the Act, 15 U.S.C. 78f(b)(4).

[16] *See e.g.,* Concept Release (discusses the various venues where trades are executed).

[17] 15 U.S.C. 78s(b)(3)(a)(ii).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63631; File No. SR–CBOE–2010–117]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Order Router Subsidy

January 3, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on December 21, 2010, Chicago Board Options Exchange, Incorporated ("CBOE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Chicago Board Options Exchange, Incorporated ("CBOE" or "Exchange") proposes to extend an existing program, under which it currently makes subsidy

payments to CBOE Trading Permit Holders that provide certain order routing functionalities to other Trading Permit Holders and/or use such functionalities themselves, to broker-dealers that are not CBOE Trading Permit Holders. The text of the [sic] proposed rule change is available on the Exchange's Web site (*http://www.cboe.org/legal*), at the Exchange's Office of the Secretary and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. CBOE has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to permit CBOE to extend its program under which it enters into subsidy arrangements with persons that provide certain order routing functionalities to other persons and/or use such functionalities themselves. Under the program as currently in effect, CBOE establishes such arrangements only with Trading Permit Holders (each, a "Participating TPH"), and makes payments to subsidize their costs associated with providing order routing functionalities only to other CBOE TPHs, as well as with using such functionalities themselves.[1]

CBOE proposes to extend the program in two related respects. First, CBOE proposes to extend the program to enable CBOE to establish such subsidy arrangements with broker-dealers that are not CBOE TPHs (each, a "Participating Non-CBOE TPH"). (The term "Participant" as used in this filing refers to either a Participating Non-CBOE TPH or a Participating CBOE TPH.) Second, CBOE proposes to extend the program to permit a Participant to receive subsidy payments for providing an order routing functionality to broker-dealers that are not CBOE TPHs.

SR–CBOE–2007–34 includes a description of the features that an order routing functionality of a Participating CBOE TPH must have, and the performance requirements that the order routing functionality must satisfy, in order to qualify for the program.[2] The order routing functionality of a Participating Non-CBOE TPH would be required to have the same features and satisfy the same requirements.

CBOE's subsidy program provides that a Participating CBOE TPH may elect to have CBOE perform certain marketing services and/or billing services on behalf of the Participating CBOE TPH.[3] These elections would also be available to a Participating Non-CBOE TPH. As with a Participating CBOE TPH, if a Participating Non-CBOE TPH elects to have CBOE perform marketing services on its behalf, the amount that CBOE would pay the Participant for orders routed through the Participant's system and executed on CBOE would be reduced from $0.04 per contract to $0.03 per contract.[4] Also as with a Participating CBOE TPH, if a Participating Non-CBOE TPH elects to have CBOE perform the service of billing CBOE TPHs with respect to the use of the Participant's router, the Participant would pay CBOE a service fee of one percent of the fees collected by CBOE for that TPH.

CBOE currently assigns an identification code to each Participating CBOE TPH for use on orders that are subject to the subsidy program. CBOE would assign such a code to each Participating Non-CBOE TPH. A Participating Non-CBOE TPH, or a party using a Participant's order routing functionality that is not a CBOE TPH, would need to route its orders to CBOE through a CBOE TPH—that is, would need to "give up the name" of a CBOE TPH. The use of these identification codes would provide CBOE with the information that it would need to account for the subsidy payments due to Participating Non-CBOE TPHs as it does for the payments due to Participating CBOE TPHs.

CBOE stated in SR–CBOE–2007–34, and affirmed in SR–CBOE–2008–27, that nothing about the subsidy program would relieve any CBOE TPH that is using an order routing functionality whose provider is participating in the program from complying with its best execution obligations.[5] This would continue to be true with respect to all users both CBOE TPH broker-dealers and non-CBOE TPH broker-dealers of order routing functionalities whose providers participate in the program. Specifically, just as with any customer order and any other routing functionality, any user whether or not a CBOE TPH of an order routing functionality whose provider is participating in the program would have an obligation to consider the opportunities for price improvement at various markets and whether routing a customer order through an order router having the features specified by CBOE would allow for access to such opportunities if readily available.[6] Moreover, any user whether or not a CBOE TPH of an order router functionality whose provider is participating in the program would need to conduct best execution evaluations on a regular basis, at a minimum quarterly, that include its use of any router whose provider is participating in the program.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 ("Act"),[7] in general, and furthers the objectives of Section 6(b)(4)[8] of the Act in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and other persons using its facilities.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not

[1] The current CBOE order router subsidy program is described in SR–CBOE–2007–34. *See* Securities Exchange Act Release No. 55629 (April 13, 2007), 72 FR 19992 (April 20, 2007) (SR–CBOE–2007–34). Additionally, the description of the current program was clarified in SR–CBOE–2008–27. *See* Securities Exchange Act Release No. 57498 (March 14, 2008), 73 FR 55 [sic] (March 20, 2008) (SR–CBOE–2008–27).

[2] SR–CBOE–2007–34, pp. 3–4 [sic]. Two of the features that an order routing functionality must have in order to qualify for the program and that are relevant to the best execution obligations of users of the functionality are described below in footnote 6.

[3] SR–CBOE–2007–34, p. 5 [sic].

[4] *See* Securities Exchange Act Release No. 62432 (July 1, 2010), 75 FR 131 [sic] (July 9, 2010) (SR–CBOE–2010–66).

[5] SR–CBOE–2007–34, pp. 5–6 [sic]; SR–CBOE–2008–27, p 4.

[6] CBOE's functional requirements state that, in order to be eligible for the subsidy program, an order router must (1) cause the default destination for an order to be the U.S. options exchange with the best bid or offer, except CBOE must be the default destination exchange for the individually executed marketable orders if CBOE is at the national best bid or offer, but (2) give the user the ability to override the default destination for any order on a manual, order-by-order, basis. CBOE believes that these requirements enable any user of a participating order router to comply with its best execution obligations.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

necessary or appropriate in furtherance of purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[9] of the Act and subparagraph (f)(2) of Rule 19b–4[10] thereunder, because it establishes a due, fee, or other charge imposed by CBOE on any person in that the subsidy arrangement relates to fees charged by certain order routing system providers for use of their routing systems.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2010–117 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2010–117. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2010–117 and should be submitted on or before January 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–92 Filed 1–6–11; 8:45 am]

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[9] 15 U.S.C. 78s(b)(3)(A).

[10] 17 CFR 240.19b–4(f)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63632; File No. SR–BATS–2010–038]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

January 3, 2011

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on December 21, 2010, BATS Exchange, Inc. (the "Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify its fee schedule applicable to Members[5] of the Exchange pursuant to BATS Rules 15.1(a) and (c). While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on January 3, 2011.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the "Options Pricing" section of its fee schedule to: (i) Modify its pricing for Customer[6] orders by decreasing the fee for removing liquidity from the Exchange and increasing the rebate for adding liquidity to the Exchange; (ii) add a rebate specifically for orders that set either the national best bid (the "NBB") or the national best offer (the "NBO") where the Member meets certain

[5] A Member is any registered broker or dealer that has been admitted to membership in the Exchange.

[6] As defined on the Exchange's fee schedule, the term "Customer" applies to any transaction identified by a member for clearing in the Customer range at the OCC.

average daily volume requirements; (iii) modify its pricing for Firm [7] and Market Maker [8] orders by increasing the fee for all orders that remove liquidity while also increasing the rebate for orders that add liquidity by either $0.05 or $0.15 per contract depending on the capacity of the remover of the liquidity; (iv) modify its pricing for Customer Directed ISO [9] orders; and (v) establish fees that will apply to all best execution routing strategies offered by the Exchange [10] and to Destination Specific Order [11] routing strategies in order to eliminate the disparate pricing between the two types of routing.

(i) Customer Pricing

The Exchange currently charges $0.30 per contract for all orders that remove liquidity from the BATS Exchange options market ("BATS Options") and pays $0.20 per contract for all orders that add liquidity to BATS Options. The Exchange proposes to both lower the fee for removing liquidity to $0.25 per contract and raise the rebate for adding liquidity to $0.25 for Customer orders. The Exchange believes that this change will generate an increase in Customer order flow and will provide more liquidity on the Exchange.

(ii) NBBO Setter Rebate

The Exchange proposes to adopt for its options platform a $0.50 per contract rebate upon execution for all orders that add liquidity that sets either the NBB or NBO (the "NBBO Setter Rebate") [12] so long as the Member submitting the order achieves an average daily volume of 20,000 contracts executed on the BATS Options book for the calendar month. Average daily volume will be calculated by taking the total number of contracts traded on the Exchange (which excludes routed orders) during the calendar month by the Member divided by the number of trading days in the month. For example, in January of 2011, a month with twenty (20) trading days, a Member must trade at least 400,000 contracts (20 trading days multiplied by 20,000 contracts per day) in the month to be eligible for the NBBO Setter Rebate. If a Member meets this volume requirement, all of the Member's orders that set the NBB or NBO that were executed in January would be eligible for the NBBO Setter Rebate. The NBBO Setter Rebate supersedes any other applicable liquidity rebates.

The Exchange believes that the proposed NBBO Setter Rebate is analogous to similar proposals designed to encourage market participants to submit aggressively priced orders previously implemented at other options exchanges.[13] The Exchange also believes that its proposed use of a volume threshold to qualify for the rebate is substantively identical to tiered pricing structures that are in place at other exchanges.[14] Additionally, the Exchange believes that the proposed NBBO Setter Rebate will incentivize the entry of more aggressive orders which will create tighter spreads, benefitting both Members and public investors.

(iii) Firm and Market Maker Pricing

As mentioned above, the Exchange currently charges $0.30 per contract for orders that remove liquidity and pays $0.20 per contract for orders that add liquidity. The Exchange proposes to raise the fee for removing liquidity to $0.35 for Firm and Market Maker orders. The Exchange also proposes to increase the rebate for Firm and Market Maker orders that are removed by Customer orders to $0.25 per contract and to increase the rebate for orders that are removed by Firm or Market Maker orders to $0.35 per contract. The removing Member's fee will be determined without regard to the capacity of the adding party.

The Exchange believes that the proposed change to the Firm and Market Maker pricing will encourage Firms and Market Makers to add more liquidity to the Exchange. The Exchange also believes that, because Members can neither see the capacity of orders in the Exchange's order book nor determine the capacity of the Member that removes an order,[15] the proposal will not disadvantage public investors or Members. Lastly, the Exchange believes that the proposed change to the fee schedule is substantively similar to a pricing plan in place at NASDAQ OMX PHLX.[16]

(iv) Directed ISO Pricing

The Exchange currently charges $0.50 per contract for a Customer Directed ISO transaction and $0.60 per contract for Firm and Market Maker Directed ISO transactions. The Exchange proposes to further simplify its pricing for Directed ISOs by setting flat rates for Directed ISOs that bypass the Exchange's order book and execute at away venues, regardless of capacity. As proposed, the charge for all Directed ISO transactions will be $0.60 per contract.

(v) Routing Pricing

The Exchange proposes to adjust its fees for options order routing and simplify its routing pricing by eliminating the different pricing between Destination Specific Orders and Standard Best Execution Routing. Currently, the Exchange charges a flat fee per contract for standard routing and a fee based on the pricing model of the destination exchange for Destination Specific Orders. In most instances, the pricing for Destination Specific Orders results in Members being charged lower execution fees than if the orders were routed directly by the Member to an away venue. Rather than continuing to subsidize its Members' routing strategies, the Exchange proposes to adjust routing fees to more closely reflect the Exchange's cost of executing those orders at the away markets. Specifically, the Exchange proposes to assess a routing fee of $0.54 per contract for all Firm and Market Maker orders that are routed to any away exchange pursuant to Standard Best Execution Routing or Destination Specific Order

[7] As defined on the Exchange's fee schedule, the term "Firm" applies to any transaction identified by a member for clearing in the Firm range at the OCC.

[8] As defined on the Exchange's fee schedule, the term "Market Maker" applies to any transaction identified by a member for clearing in the Market Maker range at the OCC.

[9] As defined in BATS Rule 21.1(d)(12).

[10] The Exchange's routing strategies are defined in BATS Rule 21.9(a)(2).

[11] As defined in BATS Rule 21.1(d)(7).

[12] An order that is entered at the most aggressive price both on the BATS Options book and according to then current OPRA data will be determined to have set the NBB or NBO for purposes of the NBBO Setter Rebate without regard to whether a more aggressive order is entered prior to the original order being executed.

[13] *See* Securities Exchange Act Release No. 61869 (April 7, 2010), 75 FR 19449 (April 14, 2010) (SR–ISE–2010–25)(notice of filing and immediate effectiveness to amend fees applicable to the International Securities Exchange, including providing increased rebates to market makers for being on the NBB or NBO for at least 80% during a given month); Securities Exchange Act Release No. 61987 (April 27, 2010), 75 FR 24771 (May 5, 2010) (SR–C2–2010–001)(notice of filing and immediate effectiveness to establish fees applicable to C2 Options Exchange, including providing Preferred Market Makers with participation entitlements when they are at the NBBO, regardless of time priority). The Commission notes that Securities Exchange Act Release No. 61987 did not establish any new fees.

[14] *See* Securities Exchange Act Release No. 57253 (February 1, 2008), 73 FR 7352 (February 7, 2008) (SR–Phlx–2008–08)(notice of filing and immediate effectiveness to amend fees applicable to the Philadelphia Stock Exchange, including adopting a tiered floor broker options subsidy based on meeting specified trading volume requirements).

[15] The Exchange notes that its proposed amendment to Rule 21.1 from Securities Exchange Act Release No. 63403 (December 1, 2010) (SR–BATS–2010–34) to add directed orders will not be subject to the proposed Firm and Market Maker Pricing. The Exchange intends to file a separate fee filing upon approval of the proposed amendment to implement directed order pricing.

[16] *See* Securities Exchange Act Release No. 57253 (February 1, 2008), 73 FR 7352 (February 7, 2008) (SR–Phlx–2008–08)(notice of filing and immediate effectiveness to amend fees applicable to the Philadelphia Stock Exchange, including adopting a tiered subsidy that does not apply to Customer-to-Customer transactions).

routing. The Exchange proposes to assess the following per contract fees for Customer orders that are routed to the named away exchange: $0.05 for all orders in non-"Make/Take" issues,[17] if applicable, routed to NYSE Amex, NYSE Arca, the Boston Options Exchange, the Chicago Board Options Exchange, the International Stock Exchange, or NASDAQ OMX PHLX; $0.20 for all orders routed to the Chicago Board Options Exchange 2; $0.25 for all orders routed to the International Stock Exchange in Make/Take issues; $0.29 for all orders routed to NASDAQ OMX PHLX in Make/Take issues; $0.48 for all orders routed to NASDAQ Options Market; and $0.49 for all orders routed to NYSE Arca in Make/Take issues.

The Exchange believes that the proposed routing fees are competitive, fair and reasonable, and non-discriminatory in that they approximate the cost to the Exchange of executing routed orders at an away market and are similar to those fees charged by other exchanges. The Exchange also believes that Members will benefit from the simplicity of the pricing structure.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[18] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4)[19] of the Act, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. As described below, the Exchange believes that its fees and credits are competitive with those charged by other venues.

The various changes to Exchange execution fees, execution rebates and routing fees proposed by this filing are intended to attract order flow to BATS Options by offering competitive pricing, especially for those who add liquidity that sets the NBB or NBO. Most of the changes the Exchange has proposed to its execution fees and rebates will result in reduced fees or increased payments that will benefit Members due to the obvious economic savings and increased revenue those Members will receive and the potential of increased available liquidity at the Exchange. The Exchange notes that it does not currently operate any auctions through which orders are held and broadcast to its membership, nor does the Exchange engage in any payment for order flow practices. Rather, the Exchange is proposing to enhance its transparent market structure with an easy to understand and transparent pricing structure by adding incentives for aggressive quoting. The Exchange believes that its proposed routing rates are, on average, better than or equal to the fees a market participant would pay if routing through another market center. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. Also, although routing options are available to all Members, Members are not required to use the Exchange's routing services, but instead, the Exchange's routing services are completely optional. Members can manage their own routing to different options exchanges or can utilize a myriad of other routing solutions that are available to market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has been designated as a fee change pursuant to Section 19(b)(3)(A)(ii) of the Act[20] and Rule 19b–4(f)(2) thereunder,[21] because it establishes or changes a due, fee or other charge imposed on members by the Exchange. Accordingly, the proposal is effective upon filing with the Commission.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–BATS–2010–038 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2010–038. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2010–038 and should be submitted on or before January 28, 2011.

[17] As defined on the fee schedule, Make/Take pricing refers to executions at the identified Exchange under which "Post Liquidity" or "Maker" rebates ("Make") are credited by that exchange and "Take Liquidity" or "Taker" fees ("Take") are charged by that exchange.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(4).

[20] 15 U.S.C. 78s(b)(3)(A)(ii).

[21] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–93 Filed 1–6–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–63630; File No. SR–BATS–2010–039]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

January 3, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 22, 2010, BATS Exchange, Inc. (the "Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify its fee schedule applicable to Members[5] and non-members of the Exchange pursuant to BATS Rules 15.1(a) and (c). Pursuant to the proposed rule change, the Exchange will commence charging fees to Members and non-members for 10G direct circuit connections, change pricing for certain other physical ports, and begin passing through in full certain hardware expenses incurred by the Exchange that are directly related to completing a cross-connect. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on January 3, 2011.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to establish fees for direct 10G circuit connections, to raise the monthly fees for "physical" ports into the Exchange at the data centers where the Exchange's servers are located, and to pass through in full any hardware costs or connectivity fees incurred by the Exchange that are directly related to completing a cross-connect where the cost or fee exceeds $1,000. The Exchange already provides Members and non-Members four pairs[6] of 1G physical ports free of charge and charges $2,000 per month for each additional single physical port.

The Exchange proposes to provide the option to connect directly with the Exchange via 10G physical ports to any Member or non-member that has been approved to connect to the Exchange. Due to the infrastructure costs associated with providing the additional bandwidth for 10G physical ports, the Exchange proposes to charge $2,500 per month for each single physical 10G port provided by the Exchange to any Member or non-member in any data center. The Exchange's proposal is intended to permit those Members and non-members that require additional bandwidth and wish to establish 10G physical ports to do so if such constituent is willing to pay for such ports. The Exchange notes that other market centers provide similar services to their Members and non-members.[7]

The Exchange also proposes to increase the fee for each 1G physical port used by Members and non-members in excess of the four ports provided free of charge from $2,000 per port each month to $2,500 per port each month. The proposal is intended to account for increasing infrastructure costs associated with providing physical ports while at the same time permitting those Members and non-members that wish to establish additional physical ports do so if such constituents are willing to pay for such ports. Based on the proposal, the change applies to all Exchange constituents with 1G physical connections, including Members that obtain ports for direct access to the Exchange, non-member service bureaus that act as a conduit for orders entered by Exchange Members that are their customers, Sponsored Participants, and market data recipients. There are zero non-members and very few Members that currently require more than four physical ports for their operations related to the Exchange and thus, the proposal should not affect many of the Exchange's constituents.

Lastly, the Exchange proposes to pass through in full any hardware costs or connectivity fees incurred that are directly related to completing a cross-connect where the expense to the Exchange billed by a third party exceeds $1,000. The Exchange proposes to pass through the expense as an alternative to the flat installation fees charged by the Exchange's primary competitors. The Exchange does not anticipate that passing through these expenses will affect many of the Exchange's constituents, because the majority of cross-connect completions cost less than $1,000. For this reason, the Exchange proposes to pass-through the charges associated with cross-connect completions that cost more than $1,000 rather than to subsidize these expensive completions by charging an installation fee for all completions regardless of their cost.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[8] in that it

[22] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] A Member is any registered broker or dealer that has been admitted to membership in the Exchange.

[6] Each pair of ports consists of one port at the Exchange's primary data center and one port at the Exchange's secondary data center.

[7] *See* Securities Exchange Act Release Nos. 62663 (August 9, 2010), 75 FR 49543 (August 13, 2010) (SR–NASDAQ–2010–077) (order approving fees for both 1G and 10G non-co-located port connections); Securities Exchange Act Release No. 62681 (August 10, 2010), 75 FR 50020 (August 16, 2010) (SR–EDGA–2010–06) (order approving fees for both 1G and 10G port connections).

[8] 15 U.S.C. 78f(b)(4).

provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The Exchange believes that its fees and credits are competitive with those charged by other venues. Finally, the Exchange believes that the proposed rates are equitable in that they apply uniformly to all Members and non-members.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) of the Act [9] and Rule 19b–4(f)(2) thereunder,[10] the Exchange has designated this proposal as establishing or changing a due, fee, or other charge applicable to the Exchange's Members and non-members, which renders the proposed rule change effective upon filing.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File Number SR–BATS–2010–039 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BATS–2010–039. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro/shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–BATS–2010–039 and should be submitted on or before January 28, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–91 Filed 1–6–11; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 240.19b–4(f)(2).

[11] *See* Section 916 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which amended paragraph (A) of Section 19(b)(3) of the Act by inserting the phrase "on any person, whether or not the person is a member of the self-regulatory organization" after "due, fee or other charge imposed by the self-regulatory organization." As a result, all SRO rule proposals establishing or changing dues, fees, or other charges are immediately effective upon filing regardless of whether such dues, fees, or other charges are imposed on members of the SRO, non-members, or both.

[12] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2011–0003]

Establishment of an Emergency Relief Docket for Calendar Year 2011

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Notice of establishment of public docket.

SUMMARY: This Notice announces the establishment of FRA's emergency relief docket (ERD) for calendar year 2011. The designated ERD for calendar year 2011 is docket number FRA–2011–0003.

ADDRESSES: See Supplementary Information section for further information regarding submitting petitions and/or comments to Docket No. FRA–2011–0003.

SUPPLEMENTARY INFORMATION: On May 19, 2009, FRA published a direct final rule addressing the establishment of ERDs and the procedures for handling petitions for emergency waivers of safety rules, regulations, or standards during an emergency situation or event. 74 FR 23329. That direct final rule became effective on July 20, 2009 and made minor modifications to § 211.45 to the FRA's Rules of Practice published at 49 CFR Part 211. Paragraph (b) of § 211.45 provides that each calendar year FRA will establish an ERD in the publicly accessible DOT docket system (available on the internet at *http://www.regulations.gov).* Paragraph (b) of § 211.45 further provides that FRA will publish a notice in the **Federal Register** identifying by docket number the ERD for that year. As noted in the rule, FRA's purpose for establishing the ERD and emergency waiver procedures is to provide an expedited process for FRA to address the needs of the public and the railroad industry during emergency situations or events. This Notice announces that the designated ERD for calendar year 2011 is docket number FRA–2011–0003.

As detailed § 211.45, if the FRA Administrator determines that an emergency event as defined in 49 CFR 211.45(a) has occurred, or that an

imminent threat of such an emergency occurring exists, and public safety would benefit from providing the railroad industry with operational relief, the emergency waiver procedures of 49 CFR 211.45 will go into effect. In such an event, the FRA Administrator will issue a statement in the ERD indicating that the emergency waiver procedures are in effect and FRA will make every effort to post the statement on its Web site *http://www.fra.dot.gov/.* Any party desiring relief from FRA regulatory requirements as a result of the emergency situation should submit a petition for emergency waiver in accordance with 49 CFR 211.45(e) and (f). Specific instructions for filing petitions for emergency waivers in accordance with 49 CFR 211.45 are found at 49 CFR 211.45(f). Specific instructions for filing comments in response to petitions for emergency waivers are found at 49 CFR 211.45(h).

Privacy

Anyone is able to search all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 665, Number 7, Pages 19477–78). The statement may also be found at *http://www.dot.gov/privacy.html.*

Issued in Washington, DC, on January 3, 2011.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2011–125 Filed 1–6–11; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0176; Notice 1]

Mitsubishi Motors North America, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

Mitsubishi Motors North America, Inc. (Mitsubishi) [1] has determined that an unknown number of replacement seat belts that it imported do not include the installation, usage and maintenance instructions required by paragraphs S4.1(k) and S4.1(l) of Federal Motor Vehicle Safety Standard (FMVSS) No. 209, *Seat Belt Assemblies.* Mitsubishi filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports* on October 25, 2010.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Mitsubishi has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Mitsubishi's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Mitsubishi explained that an unknown number of nonconforming seat belt assemblies were sold by Mitsubishi to its authorized dealers in the United States for resale and replacement purposes.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance.

Paragraphs S4.1(k) and S4.1(l) of FMVSS No. 209 requires:

(k) *Installation instructions.* A seat belt assembly, other than a seat belt assembly installed in a motor vehicle by an automobile manufacturer, shall be accompanied by an instruction sheet providing sufficient information for installing the assembly in a motor vehicle. The installation instructions shall state whether the assembly is for universal installation or for installation only in specifically stated motor vehicles, and shall include at least those items specified in SAE Recommended Practice J800c, "Motor Vehicle Seat Belt Installations," November 1973. If the assembly is for use only in specifically stated motor vehicles, the assembly shall either be permanently and legibly marked or labeled with the following statement, or the instruction sheet shall include the following statement:

This seat belt assembly is for use only in [insert specific seating position(s), e.g., "front right"] in [insert specific vehicle make(s) and model(s)].

(l) *Usage and maintenance instructions.* A seat belt assembly or retractor shall be accompanied by written instructions for the proper use of the assembly, stressing particularly the importance of wearing the assembly snugly and properly located on the body, and on the maintenance [o]f the assembly and periodic inspection of all components. The instructions shall show the proper manner of threading webbing in the hardware of seat belt assemblies in which the webbing is not permanently fastened. Instructions for a nonlocking retractor shall include a caution that the webbing must be fully extended from the retractor during use of the seat belt assembly unless the retractor is attached to the free end of webbing which is not subjected to any tension during restraint of an occupant by the assembly. Instructions for Type 2a shoulder belt shall include a warning that the shoulder belt is not to be used without a lap belt.

Mitsubishi described the noncompliance as the failure to provide installation, use and maintenance instructions with the seat belt assemblies as required in FMVSS No. 209 S4.1(k) and S4.1(l).

Mitsubishi argues that this noncompliance is inconsequential to motor vehicle safety for the following reasons:

(1) The service seat belt assemblies in question are only made available to Mitsubishi authorized dealerships for their use or subsequence resale. The Mitsubishi parts ordering system used by Mitsubishi dealers clearly identifies the correct service seat belt components for any given model/model year/seat position combination and the parts are unique to each seat belt and designed to assemble properly only in their intended application.

(2) When ordering Mitsubishi replacement seat belt parts, the dealer must refer to the Mitsubishi parts catalog to identify the ordering part number with the information on the specific vehicle model type, location and model year. Each replacement seat belt assembly is packaged individually with a specific part number label to ensure shipping the correct parts. Dealers routinely confirm that the part received matches their order to validate that the correct parts were received.

(3) Installation instructions for seat belts are readily available in the Mitsubishi workshop manuals. Technicians at Mitsubishi dealerships that replace seat belts have access to the installation instruction information in the workshop manual. Installers other than Mitsubishi dealership technicians also have seat belt installation information available in the workshop manuals and are available on the Mitsubishi Service Web site. As a result, the seat belt parts can be successfully installed with the information already available even though installation instructions were not accompanied in the replacement seat belt assemblies.

(4) Instructions for proper use and maintenance are described in the owner's manual which is installed in each vehicle. Therefore, incorrect usage

[1] Mitsubishi Motors North America, Inc. (Mitsubishi), is organized under the laws of the state of California. Mitsubishi manufactures and imports motor vehicles and replacement equipment.

and maintenance by the vehicle owner is highly unlikely.

Mitsubishi is also not aware of any customer or field reports of replacement seat belt assemblies being incorrectly installed in the subject applications as a result of the absence of the installation instructions in the service part. Mitsubishi also is not aware of any reports requesting the installation instruction, which is believed to be indicative of the availability of this information from the other sources mentioned above.

Finally, Mitsubishi has taken action to ensure that all replacement seat belt assemblies are packaged with the required installation instructions and has corrected all the replacement seat belt assemblies in the inventory for shipment to dealers.

In view of the above, Mitsubishi believes that the described noncompliance with FMVSS No. 209 is inconsequential and does not present a risk to motor vehicle safety. Thus, Mitsubishi requests that its petition, to exempt it from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120, should be granted.

Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. By mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

b. By hand delivery to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 am to 5 pm except Federal Holidays.

c. Electronically: By logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/*. Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: February 7, 2011.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at CFR 1.50 and 501.8).

Issued on: January 3, 2011.

Claude H. Harris

Acting Associate Administrator for Enforcement.

[FR Doc. 2011–79 Filed 1–6–11; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 33 (Sub-No. 293X)]

Union Pacific Railroad Company—Abandonment Exemption—In Wright County, IA

Union Pacific Railroad Company (UP) filed a verified notice of exemption under 49 CFR 1152 subpart F—*Exempt Abandonments* to abandon a line of railroad known as Kanawha Industrial Lead, extending from milepost −0.55 to milepost −0.1, a distance of .45 miles, near Belmond, in Wright County, Iowa. The line traverses United States Postal Service Zip Code 50421.

UP has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line to be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 8, 2011, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by January 18, 2011. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 27, 2011, with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to UP's representative: Mack H. Shumate, Jr., 101 North Wacker Drive, #1920, Chicago, IL 60606.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

UP has filed a combined environmental and historic report which addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by January 14, 2011. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,500. *See* 49 CFR 1002.2(f)(25).

Transportation Board, Washington, DC 20423–0001) or by calling OEA, at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), UP shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by UP's filing of a notice of consummation by January 7, 2012, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: January 3, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2011–126 Filed 1–6–11; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. FD 35458]

Gabriel D. Hall—Corporate Family Transaction Exemption—U S Rail New York, LLC and U S Rail Corporation

Gabriel D. Hall (Applicant), an individual, has filed a verified notice of exemption under 49 CFR 1180.2(d)(3) for a transaction within a corporate family. The transaction involves the creation of U S Rail New York (USR–NY) and the acquisition by USR–NY of the leasehold rights, and construction and operation rights of U S Rail Corporation (U S Rail) related to the Brookhaven Rail Terminal.[1]

Applicant controls U S Rail, a Class III carrier, which operates in Ohio, Indiana, and New York, and U S Rail New Jersey, also a Class III carrier, which operates in New Jersey. As a result of this transaction, U S Rail will assign its construction and operation authority involving the Brookhaven Rail Terminal, together with the leasehold interest in the underlying property, to USR–NY. USR–NY will facilitate financing for the approved construction and subsequent carrier operations, while Applicant remains in control of both entities.

The exemption will be effective on January 21, 2011 (30 days after the exemption was filed).

This is a transaction within a corporate family of the type exempted from prior review and approval under 49 CFR 1180.2(d)(3). Applicant states that the transaction will not result in adverse changes in service levels, significant operational changes, or changes in the competitive balance with carriers outside the corporate family.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under §§ 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III rail carriers.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Petitions for stay will be due no later than January 14 (at least 7 days before the effective date of the exemption).

An original and 10 copies of all pleadings, referring to Docket No. FD 35458 must be filed with the Surface Transportation Board, 395 E Street, SW., Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Applicant's representative, Eric M. Hocky, 2005 Market Street, Suite 1000, Philadelphia, PA 19103.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: January 3, 2011.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Andrea Pope-Matheson,

Clearance Clerk.

[FR Doc. 2011–128 Filed 1–6–11; 8:45 am]

BILLING CODE 4915–01–P

[1] In *U S Rail Corporation—Construction and Operation Exemption—Brookhaven Rail Terminal,* FD 35141 (STB served Sept. 9, 2010), the Board granted U S Rail's construction exemption, which would connect U S Rail with the Long Island Railroad.

DEPARTMENT OF VETERANS AFFAIRS

Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board Panel for Eligibility; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Public Law 92–463 (Federal Advisory Committee Act) that the Panel for Eligibility of the Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board will meet on Monday, January 24, 2011, from 8 a.m. to 12 noon, at The St. Gregory Luxury Hotel and Suites, 2033 M Street, NW., Washington, DC.

The purpose of the Merit Review Board is to provide advice on the scientific quality, budget, safety and mission relevance of investigator-initiated research proposals submitted for VA merit review consideration. Proposals submitted for review by the Board involve a wide range of medical specialties within the general areas of biomedical, behavioral and clinical science research.

The panel meeting will be open to the public for approximately one-half hour at the start of the meeting to discuss the general status of the program. The remaining portion of the meeting will be closed to the public for the review, discussion, and evaluation of non-clinician credentials and research proposals to be performed for VA.

The closed portion of the meeting involves discussion, examination, reference to staff and consultant critiques of non-clinician credentials and research proposals. As provided by subsection 10(d) of Public Law 92–463, as amended, closing portions of a panel meeting is in accordance with 5 U.S.C., 552b(c) (6) and (9)(B).

Those who plan to attend or would like to obtain a copy of minutes of the panel meeting and roster of the participants of the panel should contact LeRoy G. Frey, Ph.D., Chief, Program Review, at Department of Veterans Affairs (121F), 810 Vermont Avenue, NW., Washington, DC 20420, or e-mail at *Leroy.frey@va.gov* or call at (202) 461–1664.

Dated: January 3, 2011.

By Direction of the Secretary.

Vivian Drake,

Acting Advisory Committee Management Office.

[FR Doc. 2011–75 Filed 1–6–11; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 76 Friday

No. 5 January 7, 2011

Part II

Commodity Futures Trading Commission

17 CFR Parts 37
Core Principles and Other Requirements for Swap Execution Facilities; Proposed Rule

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 37

RIN Number 3038–AD18

Core Principles and Other Requirements for Swap Execution Facilities

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Commodity Futures Trading Commission ("Commission" or "CFTC") is proposing new rules, and guidance and acceptable practices to implement the new statutory provisions enacted by Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act. The proposed rules, guidance, and acceptable practices, which apply to the registration and operation of a new type of regulated entity named a swap execution facility, implement the new statutory framework that, among other things, adds a new Section 5h to the Commodity Exchange Act ("CEA") concerning the registration and operation of swap execution facilities, and new Section 2(h)(8) to the CEA concerning the listing, trading and execution of swaps on swap execution facilities. The Commission requests comment on all aspects of the proposed rules, guidance and acceptable practices.

DATES: Comments must be received on or before March 8, 2011.

ADDRESSES: You may submit comments, identified by RIN number 3038–AD18, by any of the following methods:

- *Agency Web site, via its Comments Online process: http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.
- *Mail:* David A. Stawick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as mail above.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that may be exempt from disclosure under the Freedom of Information Act ("FOIA"),[1] a petition for confidential treatment of the exempt information may be submitted according to the established procedures in § 145.9.[2]

The Commission reserves the right, but shall have no obligation, to review, prescreen filter, redact, refuse, or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under FOIA.

FOR FURTHER INFORMATION CONTACT: Riva Spear Adriance, Associate Director, 202–418–5494, *radriance@cftc.gov,* or Mauricio Melara, Attorney-Advisor, 202–418–5719, *mmelara@cftc.gov,* Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

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I. Background

A. Overview

On July 21, 2010, President Obama signed the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act").[3] Title VII of the Dodd-Frank Act[4] amended the CEA[5] to establish a comprehensive new regulatory framework for swaps and security-based swaps. The legislation was enacted to reduce risk, increase transparency, and promote market integrity within the financial system by, among other things: (1) Providing for the registration and comprehensive regulation of swap dealers and major swap participants; (2) imposing clearing and trade execution requirements on standardized derivatives products; (3) creating robust recordkeeping and real-time reporting regimes; and (4) enhancing the Commission's rulemaking and enforcement authorities with respect to, among others, all registered entities and intermediaries subject to the Commission's oversight.

The Dodd-Frank Act creates a new type of regulated marketplace: "Swap execution facilities" ("SEFs"),[6] for which the Dodd-Frank Act establishes a comprehensive regulatory framework, including by: Section 733 (adding new Section 5h to the CEA to provide a regulatory framework of Commission oversight), Section 723(a)(3) (adding new Section 2(h)(8) to the CEA, to require, among other things, that swaps subject to the clearing requirement of Section 2(h)(1) of the CEA be executed either on a designated contract market ("DCM") or on a SEF, unless no DCM or SEF made the swap "available for trading"),[7] and Section 733 of the Dodd-Frank Act (adding Section 5h(a)(1), requiring that no person may operate a facility for the trading or processing of swaps unless the facility is registered as a SEF or as a DCM).

In enacting the Dodd-Frank Act, Congress directed that rules and regulations required by the provisions of Title VII be promulgated by the later of either 360 days of its enactment or, to the extent that a rulemaking is required by Dodd-Frank, not less than 60 days after the publication of that final rule.[8] Consistent with Congress' directive, this release proposes amendments to Part 37 of the Commission's regulations to

[1] 5 U.S.C. 552.

[2] 17 CFR 145.9.

[3] *See* Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (2010). The text of the Dodd-Frank Act may be accessed at *http://www.cftc.gov./LawRegulation/OTCDERIVATIVES/index.htm.*

[4] Pursuant to Section 701 of the Dodd-Frank Act, Title VII may be cited as the "Wall Street Transparency and Accountability Act of 2010."

[5] 7 U.S.C. 1 *et seq.*

[6] This new regulatory framework includes: (i) Registration, operation and compliance requirements for SEFs and (ii) fifteen core principles. Applicants and registered SEFs are required to comply with the core principles as a condition of obtaining and maintaining their registration as a SEF. The definition of swap execution facility is added in Section 721 of the Dodd-Frank Act, amending Section 1a of the CEA. 7 U.S.C. 1a(50).

[7] *See* Section 723 of the Dodd-Frank Act.

[8] *See* Section 754 of the Dodd-Frank Act.

implement Sections 723(a)(3) and 733 of the Dodd-Frank Act.[9]

B. The Dodd-Frank Act

Section 723(a)(3) of the Dodd-Frank Act amends Section 2(h) of the CEA, providing that, with respect to transactions involving a swap subject to the clearing requirement of paragraph 2(h)(1), counterparties must execute the transaction on a DCM or a SEF.[10] This "exchange trading" requirement does not apply if no DCM or SEF "makes the swap available to trade" or if the exceptions to the clearing requirement apply.[11]

Section 733 of the Dodd-Frank Act adopts new Section 5h of the CEA, providing that: (i) No person may operate a facility for the trading or processing of swaps, unless the facility is registered as a SEF or as a DCM; (ii) to be registered and maintain registration, a SEF must comply with fifteen enumerated core principles and any requirement that the Commission may impose by rule or regulation; and (iii) the Commission has the authority to prescribe rules governing the regulation of SEFs.

The proposed regulations, guidance and acceptable practices will implement the regulatory obligations that each SEF must meet in order to comply with Section 5h of the CEA both initially upon registration and on an ongoing basis. The Commission requests comments on all aspects of its proposal.

[9] *See* Section 754 of the Dodd-Frank Act. Please also note that Section 734 of the Dodd-Frank Act deletes the provision of the CEA that provided for Derivatives Transaction Execution Facilities ("DTEFs"), which previously were regulated under Part 37, replacing those provisions with regulations establishing the regulatory requirements for SEFs.

[10] *See* Section 2(h)(8) of the CEA, as enacted by Section 723(a)(3) of the Dodd-Frank Act. The Dodd-Frank Act also eliminates the swaps exemption under former Section 2(g) of the CEA, supporting the requirement that trading and processing of cleared swaps must occur on a DCM or a SEF as well as expanding the types of products that can be listed and traded on a DCM to include swaps. The Commission is proposing provisions for the trading of swaps on a DCM in a separate rulemaking. *See also* Notice of Proposed Rulemaking Relating to Core Principles and Other Requirements for Designated Contract Markets approved for publication by the Commission at an open meeting on Dec. 1, 2010 and expected to be published shortly in the **Federal Register** (to be codified at 17 CFR part 38) (the "DCM NPRM"). This Notice is available at *http://www.cftc.gov/ucm/groups/public/@newsroom/documents/file/federalregister120110b.pdf* (last visited on Dec. 8, 2010).

[11] *See* Section 2(h)(8)(B) of the CEA, as enacted by Section 723(a)(3) of the Dodd-Frank Act. Newly amended Section 2(h)(7) of the CEA provides for exceptions to the clearing requirement when one of the counterparties to a swap (i) is not a financial entity, (ii) is using the swap to hedge or mitigate commercial risk, and (iii) notifies the Commission how it meets its financial obligations associated with entering into a non-cleared swap.

II. The Proposed Regulations, Guidance and Acceptable Practices

A. Adoption of New Regulations, Guidance and Acceptable Practices

The Dodd-Frank Act amended the CEA to provide that, under new Section 5h, the Commission may in its discretion determine by rule or regulation the manner in which DCMs and SEFs comply with the core principles. In consideration of the novel nature of SEFs and also based on its experience in overseeing DCMs' compliance with core principles, the Commission carefully assessed which SEF core principles would benefit from regulations, providing legal certainty and clarity to the marketplace, and which core principles would benefit from guidance or acceptable practices, where flexibility is more appropriate. Based on that evaluation, the Commission is proposing a combination of regulations, guidance and acceptable practices for the oversight and regulation of SEFs.

B. Proposed General Regulations Under Part 37

The Commission is proposing to organize Part 37 to include new subparts A through P. Proposed Subpart A would include general § 37.1 through 37.11.[12] While in this rulemaking, the Commission is proposing §§ 37.1 through 37.11, it notes that § 37.19, addressing conflicts of interest, was proposed in a separate rulemaking.[13] Subparts B through P would establish relevant regulations applicable to each of the 15 core principles.[14]

1. Subpart A—General Provisions

a. Scope—Proposed § 37.1

Proposed § 37.1 provides that Part 37 will apply to entities that are registered SEFs or that are submitting an application for SEF registration under Section 5h of the CEA, and clarifies that Part 37 does not restrict the eligibility of SEFs to operate under the provisions of Parts 38 or 49 of this Chapter.

b. Applicable Provisions—Proposed § 37.2

Proposed § 37.2 lists those Commission regulations that are applicable to SEFs, and provides that SEFs must comply with, in addition to the requirements in Part 37, the proposed Part 43 requirements regarding the real time reporting of swaps and the determination of appropriate block size for swaps, the proposed Part 45 requirements for data elements, recordkeeping and reporting of swap information to swap data repositories ("SDRs"), the proposed Part 46 requirements for business continuity and disaster recovery, the proposed Part 49 requirements regarding SDRs, and the proposed Part 151 position limits requirements.[15]

c. Requirements for Registration—Proposed § 37.3

i. Application Procedures—Proposed § 37.3(a)

Proposed § 37.3 sets forth the application and approval procedures for registration of new SEFs. The provision would require that all SEF applications, reinstatements of registrations, requests for transfer of registrations, requests for withdrawal of application for registration, and vacation of registrations must be filed electronically with the Secretary of the Commission, in the form and manner as provided by the Commission.[16]

To assist prospective applicants, the Commission proposes to include an application form under Appendix A to Part 37 ("Form SEF"); the proposed form would also be used for any updates or amendments for registration that are not required to be submitted under Part 40 of this Chapter.[17] Each applicant will be required to provide the Commission with documents and descriptions pertaining to its: (i) Business

[12] These sections apply both to applicants for registration and registered SEFs, clarify which provisions are applicable to trading on SEFs, provide for SEF registration processes (including processes for the vacation, reinstatement, and transfer of a SEF registration), and provide general requirements regarding: (i) The listing and trading of swaps; (ii) the responsibility, upon request of the Commission, to respond to requests for information and demonstrations of compliance with core principles, and to provide information and certifications upon transfers of equity interest; (iii) the enforceability of a SEF's swap transactions under certain conditions, (iv) limitations on the use of data collected for regulatory purposes, (v) the need for a board of trade that operates a trading facility that has been designated as a DCM by the Commission and also intends to operate a SEF to separately register the entity that will operate as a SEF, (vi) the appropriate execution of swaps based on the type of transaction and order interaction, and (vii) the periodic assessment of the method by which swaps are made available for trading.

[13] 75 FR 63732 (October 18, 2010).

[14] Each subpart begins with a regulation containing the language of the core principle.

[15] The Commission notes that because some of the proposed rulemakings are either ongoing or forthcoming, this proposed list of applicable sections under proposed § 37.2 may be subject to further revisions pending the final rules for each respective rulemaking.

[16] This amendment also would ensure consistency with the process used for filing rule and product submissions under Parts 38, 39 and 40 of the Commission's regulations. *See* 17 CFR Parts 38, 39 and 40.

[17] The Commission also is requiring tailored application forms for the designation of DCMs and the registration of Designated Clearing Organizations and Swap Data Repositories.

organization, (ii) financial resources, (iii) compliance program and (iv) technological capabilities.

Other than the specific requirements necessitated by the core principles, the majority of information required under the Form SEF consists of information that Commission staff has historically found necessary considering DCM applications. The Commission expects that similar information will be necessary to assess applications for SEF registration. Proposed § 37.3(a)(1) requires that, at a minimum, all applicants must complete the application form and provide the necessary information and documentation in order to initiate the SEF registration review process. The determination when a submission is complete will be at the sole discretion of the Commission. The Commission will review Form SEF and, at the conclusion of its review, by order either: (i) Grant registration; (ii) deny the application for registration; or (iii) grant registration subject to Commission-established conditions.

SEF applicants will be required to provide various documents describing the applicant's legal and financial status. SEF applicants must also submit copies of any applicable rules and regulations (as defined in § 40.1),[18] disclose any affiliates and a brief description of the nature of the affiliation, and submit copies of any agreements between the SEF and third parties that would assist the applicant in complying with its duties under the CEA.

Applicants will be required to demonstrate operational capability through documentation, including technical manuals and third party service provider agreements. Proposed § 37.3 also requires that each applicant request and obtain from the Commission a unique, extensible, alphanumeric code for the purpose of identifying the SEF pursuant to the swap recordkeeping and reporting requirements under proposed Part 45.[19]

[18] *See* 75 FR. 67282, 67292 (November 2, 2010).

[19] This requirement stems from the Commission's authority, under Section 728 of the Dodd-Frank Act, to establish standards and requirements related to reporting and recordkeeping for swaps. In particular, the Commission is required to adopt consistent data element standards for "registered entities," which include SEFs. Proposed Part 45 will set forth the recordkeeping and reporting requirements of each SEF with respect to swap transactions on or through its facility. Proposed § 37.3 codifies the obligation of SEFs to comply with the provisions of proposed Part 45. *See* 75 FR 76574 (December 8, 2010).

ii. Procedures for Temporary Grandfather Relief—Proposed § 37.3(b)

Section 754 of the Dodd-Frank Act provides that: "[u]nless otherwise provided in this title, the provisions of this subtitle [Subtitle A—Regulation of Over-the-Counter Swaps Markets] shall take effect on the later of 360 days after the date of enactment of this subtitle [*i.e.,* July 15, 2011], or, to the extent a provision of this subtitle requires a rulemaking, not less than 60 days after publication of the final rule or regulation implementing such provision of this subtitle."

The Commission anticipates that, upon the effective date of this Part 37, it may receive a large number[20] of applications for SEF registration from entities that currently provide a marketplace for the listing and trading of swaps. The Commission notes that it would be difficult to carry out and complete an appropriate and comprehensive review of all such applications during the period between publication of the final rulemaking and the effective date of this Part 37. Any consequent delay in the processing of these SEF applications could adversely impact SEF applicants, undermine the efficient implementation of the Dodd-Frank Act, create legal uncertainty for market participants and adversely affect the swaps market.

Therefore, proposed § 37.3(b) permits the Commission, upon the request of an applicant, to grant temporary grandfather relief to qualifying entities that, due to their operations, will be required to register as a SEF in order to continue operating as of the effective date of the regulations. The proposed temporary grandfather relief would be optional and would enable a qualifying entity to operate without SEF registration on a short-term basis during the pendency of the application review process on the condition that it otherwise operate in conformance with all SEF requirements under the Dodd-Frank Act. This approach is intended to avoid undue market disruption as well as to ensure continuity of the business operations of an existing entity that, at the time that Part 37 becomes effective,[21] is providing a marketplace for the trading of swaps. The temporary relief would also allow the Commission to implement registration requirements of the Dodd-Frank Act for SEFs while providing the Commission sufficient time to fully review the application of a SEF. Each SEF that qualifies for temporary relief would be subject to Section 5h of the CEA and related regulations during the period in which the Commission is reviewing the SEF's application of registration.

The Commission notes that it previously issued orders providing grandfather relief to exempt commercial markets ("ECMs") and exempt boards of trade ("EBOTs"), allowing them to continue to operate as EBOTs and ECMs after the effective date of the Dodd-Frank Act (July 15, 2011) ("ECM and EBOT grandfather relief orders").[22] The relief under proposed § 37.3(b) would be consistent with the ECM and EBOT grandfather relief orders. In addition, the Commission notes that the grandfather relief under proposed § 37.3(b) would also be available for entities that are currently operating pursuant to another exemption or exclusion provided under the CEA (prior to its amendment by the Dodd-Frank Act) as of the effective date of this Part 37.[23]

As a condition for receiving temporary grandfather relief, the applicant must: (1) File a complete application, as required under proposed § 37.3(a),[24] on the proposed application form, Form SEF, under Appendix A to Part 37; (2) notify the Commission, at the time of its submission of the application, of its interest in operating under the temporary relief; (3) provide transaction data that substantiates that the execution or trading of swaps has occurred and continues to occur on the applicant's trading system or platform at the time the applicant submits the request; and (4) provide a certification that the applicant believes that its operation on a temporary basis will meet the requirements of Part 37 of the CEA, as adopted by the Commission. Since the purpose of the temporary relief is to provide an appropriate process to ensure continuity of the business operations during the pendency of the review of an application, the temporary grandfather relief would expire on the earlier of: (i) The date that the Commission grants or denies registration of the SEF, or (ii) the

[20] The Commission notes that although the public estimate regarding the expected number of applications ranges from 30 to 40, certain market participants have noted that the number of SEFs could exceed 100.

[21] *See* Section 754 of the Dodd-Frank Act.

[22] *See* Orders Regarding the Treatment of Petitions Seeking Grandfather Relief for Exempt Commercial Markets and Exempt Boards of Trade ("ECM and EBOT grandfather relief"). 75 FR 56513 (September 10, 2010). The Commission's Orders set forth various conditions for such grandfather relief, including the filing of a relief petition and a SEF or DCM application with the Commission.

[23] *See* CEA Sections 2(d), 2(e), 2(g) and 2(h)(1)–(2).

[24] As noted above, the determination of when a submission on Form SEF is complete is at the sole discretion of the Commission.

date that the Commission rescinds the temporary relief. Additionally, the temporary relief would not be a permanent provision of Part 37. Proposed § 37.3(b) provides for a "sunset" provision so that temporary grandfather relief would terminate 365 days from the effective date of proposed § 37.3(b).

iii. Procedures for Transfer of Registration—Proposed § 37.3(d)

The Commission is proposing § 37.3(d) to formalize the procedures that a SEF must follow when requesting the transfer of its registration, in anticipation of a corporate event (*e.g.,* a merger, corporate reorganization, or change in corporate domicile) which results in the transfer of all or substantially all of the SEF's assets to another legal entity. Under proposed § 37.3(d), the SEF would submit to the Commission a request for transfer no later than three months prior to the anticipated corporate change, with a limited exception.[25]

Proposed § 37.3(d) also would require, as a condition of approval, that the SEF submit a representation that it is in compliance with the CEA, including the SEF core principles, and the Commission's regulations. In addition, the SEF would have to submit various representations by the transferee regarding its duties and obligations.

Proposed § 37.3(d) also provides that the Commission will review any requests for transfer of registration as soon as practicable, and such request will be approved or denied pursuant to a Commission order.

d. Procedures for Listing Products and Implementing Rules—Proposed § 37.4

Proposed § 37.4 conforms to the proposed changes to existing §§ 40.3 (Voluntary submission of new products for Commission review and approval) and 40.5(b) (Voluntary submission of rules for Commission review and approval),[26] in the Commission's separate rule proposal pertaining to "Provisions Common to Registered Entities."[27]

e. Information Relating to Swap Execution Facility Compliance—Proposed § 37.5

Under proposed § 37.5(a), upon request by the Commission, a SEF must file with the Commission certain information related to its business as a SEF, in the form and manner as specified by the Commission. Under proposed § 37.5(b), the Commission may demand that a SEF file a written demonstration regarding its compliance with any specified core principles. The information requested under proposed § 37.5(a) and (b) provides for information requests to entities regarding compliance with the conditions for registration made for any oversight purpose.[28]

The Commission believes that on occasion, SEFs will enter into equity interest transfers that result in a change in ownership. In those situations, Commission staff must determine whether the change in ownership will impact adversely the operations of the SEF or the SEF's ability to comply with the core principles and the Commission's regulations. The Commission is proposing § 37.5 to ensure that SEFs remain mindful of their self-regulatory responsibilities when negotiating the terms of significant equity interest transfers, and to improve the Commission staff's ability to undertake a timely and effective due diligence review of the impact, if any, of such transfers.

Proposed § 37.5(c) would require SEFs to file with the Commission a notice of the equity interest transfer of ten percent or more, with certain documents providing information on the transfer, no later than the business day[29] following the date on which the SEF enters into a firm obligation to transfer the equity interest.[30] The proposed regulation requires that the SEF keep the Commission apprised of the projected date that the transaction resulting in the equity interest transfer will be consummated, and must provide to the Commission any new agreements or modifications to the original agreement(s) filed pursuant to proposed § 37.5(c). The SEF must notify the Commission of the consummation of the transaction on the day on which it occurs. The proposed regulation will enable staff to consider whether any conditions contained in an equity transfer agreement(s) are inconsistent with the self-regulatory responsibilities of a SEF or with any of the core principles.

The Commission believes when there is a 10% or greater change in ownership, the SEF itself is the more appropriate entity to provide a certification of its continued compliance with all regulatory obligations. Accordingly, proposed § 37.5(c)(3) would require that if there is a change in ownership,[31] the SEF must certify, no later than two business days following the date on which the change in ownership occurs, that the SEF meets all of the requirements of Section 5h of the CEA and the provisions of Part 37 of the Commission's regulations.

Request for Comment:

The Commission notes that there are differences in the proposed notification requirements for changes in the ownership of SEFs, derivative clearing organizations ("DCOs"), DCMs, and SDRs.[32] The Commission requests comment on the proposed notification requirements under 37.5(c) and, more specifically, the extent to which there should be uniformity or differentiation in procedures applied to different types of registrants.

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[25] The proposed rule would require that where a SEF does not know or could not have reasonably known three months prior to the anticipated change, it shall be required to file the request as soon as it knows of the change.

[26] Proposed § 40.3 is amended to require additional information to be provided by registered entities that submit new products for the Commission's review and approval. Proposed § 40.5(b) codifies a new standard for the review of new rules or rule amendments as established under the Dodd-Frank Act.

[27] 75 FR 67282 (November 2, 2010).

[28] In this regard, for example, the Commission may request SEFs to provide information relating to their operations or their practices in connection with its general oversight responsibilities under the CEA, in connection with the Commission's formulation of statements of acceptable practice, or in connection with a particular SEF's compliance with particular core principles or other conditions of its registration.

[29] "Business day" is defined in Commission § 40.1.

[30] The Commission is proposing a 10 percent threshold because it believes that a change in ownership of such magnitude may have an impact on the operations of the swap execution facility. The Commission believes that such impact may be present even if the change in ownership does not constitute a change in control. For example, if one entity holds a minority 10 percent equity share in the SEF, it may have a more significant voice in the operation of the SEF than five entities each with a minority 2 percent equity share. Given the potential impact that a change in ownership might have on the operations of a SEF, the Commission believes that it is appropriate to require such SEF to certify after such change that it continues to comply with all obligations under the CEA and Commission regulations.

[31] The Commission's regulations consistently identify a financial or ownership interest of ten percent or more as material and indicative of the ability to influence the activities of an entity or trading in an account. *See, e.g.,* Core Principle 5, Acceptable Practices, and Core Principle 14, Application Guidance, in Appendix B to Part 38 of the Commission's regulations. 17 CFR part 38, Appendix B.

[32] *See, supra* note 10, DCM NPRM; *also* the Notice of Proposed Rulemaking Relating to Swap Data Repositories, approved for publication by the Commission at an open meeting on November 19, 2010 and expected to be published shortly in the **Federal Register** (to be codified at 17 CFR part 49). This Notice is available at *http://www.cftc.gov/stellent/groups/public/@otherif/documents/ifdocs/federalregister112210d.pdf* (last visited on Dec. 8, 2010); and other appropriate future rulemakings.

f. Enforceability of Executed Swaps—Proposed § 37.6

Proposed § 37.6 is intended to provide legal certainty to market participants transacting in swaps. Under § 37.6(a), a transaction entered into on or pursuant to the rules of a registered SEF will not be void, voidable, subject to rescission or otherwise invalidated or rendered unenforceable as a result of: (1) A violation by the registered SEF of the provisions of Section 5h of the CEA or Part 37; or (2) any Commission proceeding to alter or supplement a rule, term or condition under Section 8a(7) of the CEA, to declare an emergency under Section 8a(9) of the CEA, or any other proceeding the effect of which is to alter, supplement, or require a registered SEF to adopt a specific term or condition, trading rule or procedure, or to take or refrain from taking a specific action.

In other rules proposed by the Commission, a swap confirmation is defined as the consummation (electronically or otherwise) of legally binding documentation (electronic or otherwise) that memorializes the agreement of the counterparties to all of the terms of a swap.[33] Proposed § 37.6(b) provides that a confirmation must be in writing (whether electronic or otherwise) and must legally supersede any previous agreement (electronically or otherwise). For swaps executed on a SEF, the SEF will provide the counterparties with a definitive written record of the terms of their agreement, which will serve as a confirmation of the swap. The proposed regulation on swap confirmations would require that parties have full written agreement on all terms of a swap at the same time as execution.

g. Prohibited Use of Data Collected for Regulatory Purposes—Proposed § 37.7

In fulfilling their regulatory and compliance obligations, the Commission expects that SEFs will often require market participants to provide proprietary data or personal information. Proposed § 37.7 prohibits a SEF from using information generated by market participants for purposes of meeting regulatory and compliance obligations for marketing products or for other commercial purposes.[34] The Commission notes that nothing in this regulation prohibits a SEF from sharing such information with another SEF or DCM offering swaps for trading for regulatory purposes.

h. Boards of Trade Operating Both a Designated Contract Market and a Swap Execution Facility—Proposed § 37.8

Proposed § 37.8 implements CEA Section 5h(c) by requiring that a board of trade that operates a trading facility that has been designated as a DCM by the Commission and also intends to operate an entity for the execution or trading of swaps: (1) Must separately register such entity as a SEF under Part 37; and (2) may use the same electronic trade execution system for executing swaps that it uses for its DCM operations, provided that, the entity clearly identifies to market participants whether the execution or trading of a swaps is taking place on the DCM or the SEF.[35]

i. Permitted Execution Methods—§ 37.9

This rule proposal will provide market participants with the choice of a number of means to access the market and execute trades therein. This flexibility would allow market participants to use requests for quotes, indications of interest, or executable quotes to consummate a trade. It would allow SEFs to use a variety of different trading systems or platforms as long as market participants have the ability to access the market and execute trades as discussed below.

i. SEF Definition

The term 'swap execution facility' means a trading system or platform in which multiple participants have the ability to execute or trade swaps by accepting bids and offers made by multiple participants in the facility or system, through any means of interstate commerce, including any trading facility, that—(A) Facilitates the execution of swaps between persons; and (B) is not a designated contract market.[36]

Market participants currently use a number of different methods for transacting swaps, including: brokers who facilitate trades over the telephone (commonly referred to as "voice brokers"); hybrid voice and electronic trading systems; fully electronic inter-dealer brokerage systems; single-dealer trading platforms; various versions of "request for quote" platforms (including platforms that allow more than one customer to submit requests for quotes to, and receive responses from, multiple dealers); and order books. The Commission does not believe that all of these methods comply with the statutory definition of a SEF, especially the "multiple participant to multiple participant" requirement thereunder. Specifically, as discussed below, the Commission notes that entities offering the following services do not comply with the statutory definition of a SEF: one-to-one voice services for the execution or trading of swaps (other than for the execution of block trades),[37] single-dealer platforms, and services that solely provide for the processing of swaps.

The SEF definition requires at a minimum the existence of a "trading system or platform." The Commission notes that the terms "trading system" and "platform" are not defined under the Dodd-Frank Act or anywhere in the CEA. Based on the SEF definition under the Dodd-Frank Act, the Commission interprets trading system and platform to include, but not be limited to, the term "trading facility" as defined in CEA Section 1a(51).[38] In addition, as discussed in detail below, the Commission believes that any other method that allows multiple market participants to have the ability to execute or trade swaps by accepting

[33] *See* 75 FR 76140 (December 7, 2010); and 75 FR 76574 (December 8, 2010).

[34] The Commission notes that, in the recent notice of proposed rulemaking for Business Affiliate Marketing and Disposal of Consumer Information Rules, it proposed rules prohibiting futures commission merchants ("FCMs") (and other intermediaries) from using certain consumer information received from an affiliate to make a solicitation for marketing purposes. In addition, rules were proposed requiring FCMs to develop a written disposal program to the extent that such FCMs possess consumer information. The underlying policy for these rules is to protect the privacy of customer information. Similarly, Proposed § 37.7 is intended to protect market participants' information provided to a SEF for regulatory purposes from its use to advance the commercial interests of the SEF.

[35] Section 5h(c) of the CEA provides:

IDENTIFICATION OF FACILITY USED TO TRADE SWAPS BY CONTRACT MARKETS.—A board of trade that operates a contract market shall, to the extent that the board of trade also operates a swap execution facility and uses the same electronic trade execution system for listing and executing trades of swaps on or through the contract market and the swap execution facility, identify whether the electronic trading of such swaps is taking place on or through the contract market or the swap execution facility.

[36] CEA Section 1a(50).

[37] As proposed, a block trade is a swap of a large notional or principal amount that is transacted off-exchange, pursuant to the rules of a SEF or DCM, and that is greater than the minimum block trade size set by the SEF or DCM. As proposed, a SEF or DCM must set the minimum block size for a particular swap contract at an amount greater than the appropriate minimum block size for the appropriate category of swap instrument in which such swap contract is categorized. *See* 75 FR 76140 (December 7, 2010).

[38] *See* CEA Section 1a(51). In this context, a trading facility requires "a physical or electronic facility or system in which multiple participants have the ability to execute or trade agreements, contracts, or transactions (i) by accepting bids or offers made by other participants that are open to multiple participants in the facility or system; or (ii) through the interaction of multiple bids or multiple offers within a system with a pre-determined non-discretionary automated trade matching and execution algorithm."

bids and offers made by other multiple participants in the facility or system, through any means of interstate commerce, may qualify as an acceptable trade execution method for an entity that wishes to register as a SEF.

In order for an entity to meet the definition of a SEF and satisfy the SEF registration requirements, multiple parties must have the "ability to execute or trade swaps by accepting bids and offers made by multiple participants" and such participants must be provided impartial access to the market. The Commission believes that an acceptable SEF platform or system must provide at least a basic functionality to allow market participants the ability to make executable bids or offers and indicative quotes, and to display them to multiple parties, including all other parties participating in the SEF, if the market participants wish to do so. As set forth in proposed § 37.9(b) and discussed below, the Commission proposes that a SEF also must provide market participants with the ability to make a bid, make an offer, hit a bid, or lift an offer, and may provide the ability to request a bid and request an offer. Accordingly, market participants would not have to receive a "request for quote" [39] from another market participant in order to make a bid or offer or to execute a trade with other market participants. In addition to this basic functionality whereby market participants would have the ability to access all other market participants, a SEF could also provide a multiple-to-multiple request for quote trading system for those market participants that do not wish to display their bids, offers, or requests to all other market participants. A SEF's chosen approach(es) would be described in its registration application, to be evaluated by the Commission during the application process. Once operational, the Commission would be able to empirically evaluate the SEF's treatment of executable bids and offers as compared to responses to requests for quotes to ensure ongoing compliance with the definition of a SEF, the SEF registration requirements, and the core principles.

ii. One-to-One Voice and Single-Dealer Platforms

The Commission notes that one-to-one voice services and single-dealer platforms do not satisfy the statutory requirement under CEA Section 1a(50) that "multiple participants have the ability to execute or trade swaps by accepting bids and offers made by multiple participants in the facility or system". The nature of these types of trading systems or platforms, where transactions are negotiated or consummated via a one-to-one or one-to-many basis, do not provide the ability for participants to conduct multiple-to-multiple execution or trading. The Commission also notes that CEA Sections 5h(f)(2)(A)(ii) and (2)(B)(i) require that SEFs provide market participants with impartial access to their markets, and that SEFs must adopt rules with respect to any limitations they place on access. Entities operating either one-to-one voice services or single-dealer platforms, by definition, limit the provision of liquidity to single dealers or liquidity providers, thus excluding other participants from filling those roles, in non-compliance with the impartial market access requirements applicable to SEFs under the CEA.

iii. Processing of Swaps

In regard to entities that offer, with respect to swaps transactions, processing services exclusively, the Commission notes that Section 5h(a)(1) of the CEA states "[n]o person may operate a facility for the trading or processing of swaps, unless the facility is registered as a [SEF] or as a [DCM] under this section." In addition, Section 5h(b) states that a registered SEF may "(A) make available for trading any swap, and (B) facilitate trade processing of any swap." Although these provisions could be read to require the registration of entities that engage in trade processing (but not trade execution) as SEFs, the Commission believes that entities that operate exclusively as swap processors do not meet the SEF definition (and should not be required to register as SEFs) because: (1) They do not provide (as required by the definition) the ability to "execute or trade" a swap; and (2) the definition does not include the term "process."

iv. Trading Systems or Platforms

When determining what types of trading systems qualify to register as a SEF, the Commission takes into account, in addition to consideration of the SEF definition as discussed above, the core principles applicable to SEFs [40] as well as the goals provided in Section 733 of the Dodd-Frank Act: (1) Bringing greater pre-trade price transparency to swap transactions; and (2) bringing more swaps trading onto regulated trading systems or platforms.[41] Therefore, the Commission interprets the SEF registration requirements to necessitate that the trading system or platform: (a) Provide multiple participants with the ability to make bids and offers to other multiple participants or to accept bids or offers made by other multiple participants; (b) promote pre-trade price transparency; (c) ensure that the trading of swaps on the trading system or platform is in accordance with the SEF core principles, the registration requirements and the Commission's regulations; and (d) provide all market participants with impartial access to the SEF's market.

The Commission believes that, to register as a SEF or to maintain registration, an applicant or SEF must provide market participants with the ability to make executable quotes on either side of a swap transaction and to take the opposite side of a trade from participants who seek to enter into transactions on such contract. The "multiple participant to multiple participant" requirement, when read in conjunction with the impartial access requirement (*i.e.,* the Core Principle 2 requirement that the SEF must "provide market participants with impartial access to the market") requires that each SEF provide any market participant with the ability to make any bid or offer transparent to all other market participants of the SEF. In addition, the "ability to execute or trade" statutory provision means that the SEF must provide market participants with the ability to post both firm and indicative quotes on a centralized screen such that they can be executed or traded against by other multiple market participants. Under the proposal, it is a market participant's prerogative to make a bid or offer available to all other market participants in the trading system or platform without an invitation to join an auction process. Willing counterparties should have the ability to execute swap trades by accepting such bids or offers. The Commission believes there could be a number of ways for a SEF to provide this functionality, including but not limited to having an order book.

Additionally, SEFs must make indicative quote functionalities available, such that market participants could provide non-executable quotes or indicative quotes through the SEF that are visible and accessible to all other market participants. Such functionalities could include electronic,

[39] *See infra,* Section II.C.2.i.v for further discussion of "request for quote" systems.

[40] *See e.g.,* Sections 5h(f)(2)(A)(ii) and (2)(B)(i) (Core Principle 2, requiring the provision of impartial access). *See also infra,* Section II.C.2.a. (discussing the provision of impartial access under to Core Principle 2).

[41] *See* CEA Section 5h(e) (Stating twin goals regarding the promotion of "the trading of swaps on swap execution facilities" and "pre-trade price transparency in the swaps market").

streaming indicative quotes, or other methods for providing market participants with indicative quotes. Indicative quotes provide additional information about pricing and help inform market participants as they consider hedging and investment strategies, as well as when considering whether and how to execute a trade (either through a request for quote or through an existing executable quote). The Commission believes that indicative quotes are consistent with the statute's goal of achieving pre-trade price transparency.

The Commission believes that SEFs can utilize various trading systems and platforms that provide market participants with the ability to post executable bids or offers for display to multiple potential counterparties. A trading system or platform that provides this minimum multiple-to-multiple functionality, as described above, also may include other functionalities that provide multiple participants with the ability to access multiple market participants, but not necessarily the entire market if the participant so chooses. These may include certain request for quote systems, as described below, or other systems that meet the SEF definition and comply with the core principles.[42] Hence, although at times a market participant may desire to interact with a limited number of market participants (*i.e.,* fewer than the entire market) and are permitted to do so under the proposal, market participants that desire to access the entire market must be provided with the ability to do so as well.

v. Execution Methods

Proposed § 37.9 will allow market participants to have the choice of a number of means to access and execute within a SEF's marketplace. There would not be any requirements for pre-trade transparency for: (1) Blocks; (2) trades subject to the end user exceptions; or (3) contracts which are not "made available for trading." Thus the requirements for pre-trade transparency (*e.g.,* posting both firm and indicative quotes on a centralized electronic screen accessible to all market participants) [43] for trades executed on a SEF would only relate in the context of transactions in swaps which are: (1) Subject to the mandatory clearing requirement; (2) "made available for trading" on a SEF; and (3) too small to be a block trade under part 45. For these three types of transactions, SEFs could permit their market participants to trade via requests for quotes, indications of interest, or executable quotes.

As stated in the preceding section, Section 5h(e) of the CEA sets forth Congress' goals with respect to SEFs: The promotion of "the trading of swaps on swap execution facilities" and "pre-trade price transparency in the swaps market." [44] The Commission believes that these goals can be achieved for swap transactions that are subject to the CEA execution requirements, are made available for trading, and are not block trades by providing for the execution of such swap transactions on trading systems or platforms that give market participants the option to post both firm and indicative quotes or accept bids and offers that are transparent to the entire market.[45]

Under proposed § 37.9, applicants and registered SEFs must offer trading services to facilitate the ability of market participants to make executable bids or offers and to display them to multiple parties. Transactions may be executed by providing market participants with a number of execution methods from which to choose, including: (1) "Request for quote" systems that provide market participants the ability to interact with multiple participants but less than the entire market, as described below; (2) systems that allow market participants to display executable bids and offers on a centralized, electronic screen to the entire market; or (3) other systems that comply with the core principles.

Additionally, under the proposal, SEFs must provide a general timing requirement applicable to traders such as brokers who have the ability to execute against a customer's trade or are entering a trade for two customers on opposite sides of the transaction. Under the proposal, a broker would have to provide a minimum pause before entering the second side (whether for its own account or for a second customer), thus "showing" other market participants the terms of a request for quote from its customer, and providing other market participants the opportunity to join in the trade. The Commission proposes to require a minimum pause of 15 seconds between entry of two potentially matching customer-broker swap orders or two potentially matching customer-customer swap orders on SEFs.

(A) Request for Quote Systems

As proposed by the Commission, the steps taken by market participants in order to complete a transaction using an acceptable request for quote system are similar to the steps taken in the marketplace today (*i.e.,* a market participant transmits a request to counterparties for bids or offers and chooses to transact with one of the respondents to the request). However, to ensure that multiple participants have the ability to reach multiple counterparties, the Commission proposes to require SEFs to provide that market participants transmit a request for quote to at least five potential counterparties in the trading system or platform. The Commission notes that, under the proposal, acceptable request for quote systems offered by SEFs could be designed such that requests for quotes are visible to all market participants with access to the trading system or platform, but should permit requesters the option of making a request for quote visible to the entire market. Additionally, the proposal provides that an acceptable request for quote system may allow for a transaction to be consummated if the original request to five potential counterparties receives fewer than five responses.[46]

Under the proposal, SEFs that utilize request for quote systems must also furnish liquidity providers with the ability to post both executable bids or offers and indicative quotes. The terms of any such "resting" executable bids or offers would be displayed to the requester along with any other specific bids or offers included in the responses to its request for quote. Upon receipt of the responses and the appropriate resting bids or offers, the original requester would have the option to execute the transaction. The Commission believes that SEFs that utilize request for quote systems must ensure that any competitive resting bids or offers be taken into account and communicated to the requester along with any bids or offers included with responses to requests for quotes. While the Commission does not believe it appropriate to prescribe a method of integration as part of this rulemaking,

[42] As previously noted, one-to-one voice systems and single-dealer platforms do not satisfy the listed factors.

[43] *See also,* proposed § 37.205(b)(1).

[44] *See* CEA Section 5h(e).

[45] While currently such systems are often used by traders in order to account for counterparty risk, it is important to note that there is no counterparty risk for swaps that are cleared.

[46] The proposal also provides that request for quote systems include trading systems or platforms in which multiple market participants view real-time electronic streaming quotes, both firm and indicative, from multiple potential counterparties on a centralized electronic screen, and have the ability to accept a firm streaming quote and complete the transaction or based on an indicative streaming quote, issue a request for quote to no less than five market participants and upon receipt of a responsive quote, have the option to complete the transaction. *See* proposed § 37.9(a)(1)(v).

the Commission would expect each SEF to describe its chosen integration mechanism as part of its application.

The Commission believes its proposed approach to the use of request for quote systems by SEFs is consistent with the statute and promotes: (a) The ability of multiple participants to make bids and offers to other multiple participants or to accept bids or offers made by other multiple participants; (b) pre-trade price transparency; (c) the trading of swaps on a regulated trading system or platform in accordance with the registration requirements and the Commission's regulations; and (d) the ability for all market participants to receive impartial access to all other market participants. The Commission further believes that this feature would help encourage price competition within the market.

(B) "By Any Means of Interstate Commerce"

For block trades, swaps not subject to clearing, and bespoke or illiquid swaps, the Commission interprets the statute's language "by any means of interstate commerce" to allow execution methods that may include voice. This method of execution is consistent with the use of voice in the futures markets for executing block trades, where in light of the size of the trades, pre-trade transparency is not required. It is also possible that a SEF might choose to offer to facilitate bilateral trading for those transactions not bound by the CEA's execution requirements and, therefore, the use of voice may be acceptable. The Commission notes that with respect to these types of transactions, market participants may have an interest in choosing their counterparty in light of the credit risk involved. Voice transactions must be entered into some form of electronic affirmation system immediately upon execution.

With regard to swaps available for trading that are not blocks, trading systems or platforms facilitating the execution of such swaps via voice exclusively are not multiple participant to multiple participant and do not provide for pre-trade transparency. While not acceptable as the sole method of execution of swaps required to be traded on a SEF or DCM, the Commission believes voice would be appropriate for a market participant to communicate a message to an employee of the SEF, whether requests for quotes, indications of interest, or firm quotes. For instance, voice-based communications in the proposed SEF context may occur in certain circumstances, such as when an agent: (1) Assists in executing a trade for a client, immediately entering the terms of the trade into the SEF's electronic system; or (2) enters a bid, offer or request for quote immediately into a SEF's electronic multiple-to-multiple trading system or platform. In all cases, the employee of the SEF must promptly provide transparency and comply with audit trail requirements, including by the immediately entering into the trading system or platform any orders or requests for quote that are immediately executable, or, if not, immediately creating an electronic record with the order or request for quote entered into the trading system or platform as soon as practicable. The core principles and these rules would fully apply to such communications including but not limited to the transparency, audit trail, impartial access and standards for requests for quotes.

Request for Comment:

The Commission seeks public comment regarding the trading systems or platforms described in this section. In addition, the Commission asks the public to respond to the specific questions below.

- Does the proposal appropriately implement the statutory directive that a SEF provide multiple participants with the ability to execute or trade swaps by accepting bids and offers made by multiple participants in the facility or system? If not, how should the Commission best carry out the intent of Congress in the registration and oversight of SEFs?
- The Commission interprets the "multiple participant to multiple participant" requirement (in conjunction with the impartial access requirement) as requiring that the facility provide the ability for any market participant to make any bid or offer transparent to the entire market, if the market participant chooses to do so. Should the Commission be explicit as to the means or methods which can be used to fulfill this functionality? If so, in addition to an order book, what other means or models should be included in the final regulations?
- In light of the "multiple participant to multiple participant" requirement, the Commission has proposed that requests for quotes be requested of at least five possible respondents. Is this the appropriate minimum number of respondents that the Commission should require to potentially interact with a request for quote? If not, what is an appropriate minimum number? Some pre-proposal commenters have suggested that market participants should transmit a request for quote to "more than one" market participant. The Commission is interested in receiving public comment on this matter.
- Should the Commission determine that other models of execution satisfy the statutory "multiple participant to multiple participant" requirement as well as the pre-trade price transparency and open access policy objectives under the Dodd-Frank Act?
- Does the proposal properly implement the provision in the SEF definition regarding having the ability to execute or trade swaps "through any means of interstate commerce"?
- In general, does the proposal properly implement the CEA's goal to promote both the trading of swaps on SEFs and pre-trade price transparency? Should there be other characteristics the Commission should consider? If so, what are they?
- What level of pre-trade transparency should be required to promote price discovery, competition and the trading of swaps on SEFs? Should the Commission consider requiring a request for quote method that provides for transparency in the request for quote process in addition to the posting of any resting bids/offers on its trading system or platform? Should all orders and quotes be displayed to all participants or should alternative engagement rules apply on a pre-trade basis?
- Should SEFs be required to communicate executable bids/offers to issuers of requests for quotes? Also, should any such executable bids/offers be provided any priority during the request for quote process? Should market participants have an obligation to consider and/or execute against an executable bid/offer if it is competitive?
- Should SEFs be required to make responses to requests for quotes transparent to all market participants? If so, when should this information be provided to the market? Prior to execution? At the time of execution? Subsequent to execution?
- Would the SEF provisions in the Dodd-Frank Act support a requirement that swaps that meet a certain level of trading activity be limited to trading through order books? If so, what level of trading activity would be the appropriate level at which to mandate trading exclusively on an order book? Should any such analysis be done on a product or asset-class basis?
- Should swap processors be subject to the registration requirements for SEFs?

j. Swaps Made Available for Trading—Proposed § 37.10

The Dodd-Frank Act requires that transactions involving swaps subject to

the clearing requirement be executed on a SEF or DCM.[47] This trade execution requirement will not apply if (i) the Commission has not made a determination regarding the clearing requirement with respect to the swap,[48] (ii) an eligible counterparty availed itself of an exception to the clearing requirement and does not wish to transact the swap on a SEF or DCM, or (iii) no DCM or SEF "makes the swap available to trade."[49]

The Commission proposes to require SEFs to make periodic assessments to determine whether a swap has been made available for trading. To that end, proposed § 37.10 requires each SEF to annually conduct an assessment and provide a report to the Commission regarding the determination that the swaps it offers are made available for trading thereunder. With respect to the determination that swaps are made available to trade, the SEF may consider frequency of transactions and open interest, and any additional factors requested by the Commission.

Request for Comment:

The Commission seeks general public comment regarding the meaning of "made available for trading." In addition, the Commission asks the public to respond to the specific questions below.

- In addition to the frequency of transactions and open interest, should the Commission request that SEFs consider the number of market participants trading a particular swap? If so, should a minimum number of participants be required, for example, should the swap be traded by more than two participants? More than three?
- Should the Commission request that SEFs consider any other factors or processes to make the determination that swaps are made available for trading?

k. Identification of Non-Cleared Swaps or Swaps Not Made Available To Trade—Proposed § 37.11

The Commission acknowledges that certain market participants may desire to avail themselves of the benefits of trading on SEFs (*e.g.,* automated confirmation of trades, straight-through processing) with respect to trades that are not otherwise required to be executed on a SEF or DCM. In particular, market participants might want to effect swap transactions on SEFs or DCMs regarding swaps that have not been determined to come under the clearing mandate of Section 2(h) of the CEA, transactions that are excepted from the clearing requirements as provided under Section 2(h)(7) of the CEA, and transactions regarding swaps determined to not be available for trading pursuant to Commission § 37.10. Proposed § 37.11 requires that if a SEF determines to provide for trading of swaps that are excepted from the clearing requirements, the SEF must clearly identify to market participants that the particular swap is to be transacted pursuant to one of the applicable exemptions from execution and clearing.

C. Proposed Regulations, Guidance and Acceptable Practices for Compliance With the Core Principles

As noted above, this rulemaking establishes the relevant regulations, guidance and acceptable practices applicable to the 15 core principles. As proposed, the regulations applicable to the 15 core principles are set out in separate subparts to Part 37, Subparts B through P, which includes a codification within each subpart of the statutory language of the respective core principle. The guidance and acceptable practices are set out in Appendix B.

1. Subpart B—Core Principle 1 (Compliance With Core Principles)

Under Core Principle 1, compliance with the core principles, and any other rule or regulation that the Commission may impose under Section 8a(5) of the CEA, is a condition of obtaining and maintaining registration as a SEF.[50] The Commission proposes to codify the statutory text of Core Principle 1 in proposed § 37.100. SEFs will have reasonable discretion in establishing the manner in which they comply with the core principles.

2. Subpart C—Core Principle 2 (Compliance With Rules)

a. Background

Core Principle 2 requires a SEF to establish and enforce compliance with its rules,[51] including by: (1) Establishing various rules to deter abuses; and (2) having the capacity to detect, investigate, and enforce such rules.[52] Similarly, under Core Principle 2, a SEF must establish and enforce rules to provide any eligible contract participant ("ECP") and any independent software vendor ("ISV")[53] with impartial access to the market and to capture information that the SEF may use in establishing whether rule violations have occurred.[54] Additionally, SEF Core Principle 2 requires a SEF to establish rules governing the operations of the trading platform and provide rules relating to the mandatory clearing requirement under Section 2(h)(8).[55]The Commission proposes to implement these requirements through §§ 37.200–37.207.

Although SEFs are a new type of regulated exchange, the Commission notes that the statutory text for SEF Core Principle 2 is largely a compilation of established regulatory principles applicable to DCMs. As a result, proposed §§ 37.200–37.207, implementing SEF Core Principle 2, set forth requirements for establishing and enforcing rules, providing access, conducting trade practice surveillance, and implementing audit trail requirements and disciplinary rules, that are analogous to those found in the proposed regulations for DCM Core Principles 2, 10, and 13. In addition, proposed §§ 37.200–37.207 also address elements of Core Principle 2 that are not implicated by these DCM core principles.

b. Operation of a Swap Execution Facility and Compliance With Rules—Proposed § 37.201

Proposed § 37.201 addresses the requirement to establish and enforce rules. More specifically, the core principle requires that a SEF establish and enforce compliance with its rules.[56]A SEF is also required to

[47] CEA Section 2(h)(8).

[48] CEA Section 2(h)(1).

[49] CEA Section 2(h)(8).

[50] CEA Section 5h(f)(1)(A).

[51] CEA Section 5h(f)(2)(A).

[52] CEA Section 5h(f)(2)(C) requires SEFs to establish rules specifying trading procedures to be used in entering and executing orders traded or posted on the trading platform, including block trades. The sentence annotated by this footnote also captures 2(B).

[53] The Commission notes that examples of independent software vendors include: Smart order routers, trading software companies that develop front-end trading applications, and aggregators of transaction data. Smart order routing generally involves scanning of the market for the best-displayed price and then routing orders to that market for execution. Software that serves as a front-end trading application is typically used by traders to input orders, monitor quotations and view a record of the transactions completed during a trading session. Aggregators of transaction data provide access to news, analytics and execution services. The Commission believes that transparency and trading efficiency would be enhanced as a result of innovations in this field for market services. For instance, certain providers of market services with access to multiple trading systems or platforms could provide consolidated transaction data from such trading systems or platforms to market participants.

[54] CEA Section 5h(f)(2)(B).

[55] CEA Section 2(h)(8) requires counterparties transacting in swaps that are subject to the clearing requirement of Section 2(h) to execute the transaction on a DCM or a SEF, unless no DCM or SEF "makes the swap available to trade" or the swap transaction is subject to the clearing exception under Section 2(h)(7). The sentence annotated by this footnote captures both 2(C) and 2(D).

[56] CEA Section 5h(f)(2)(A)(i).

establish rules governing the operation of the trading platform.[57]

Proposed § 37.201 addresses these elements by requiring SEFs to establish rules governing the members' and market participants' use of their markets, including rules specifying trading procedures for entering and executing orders traded or posted on the trading platform, including block trades. Proposed § 37.201(b) further requires SEFs to establish and impartially enforce compliance with the rules of the SEF, including, but not limited to: (1) The terms and conditions of any swaps traded or processed on or through the SEF; (2) access rules for the SEF; (3) trade practice rules; (4) audit trail requirements; (5) disciplinary rules; and (6) mandatory trading requirements.

c. Access Requirements—Proposed § 37.202

Proposed § 37.202 addresses Core Principle 2's requirement that SEFs provide any ECP and any ISV with impartial access to the market, and that they adopt rules with respect to any limitations they place on access.[58] In that regard, proposed § 37.202(a) requires a SEF to provide any ECP and any ISV with impartial access to its market(s) and market services (including any indicative quote screens or any similar pricing data displays), which includes establishing criteria that are impartial, transparent, and applied in a fair and nondiscriminatory manner and levying equal fees for participants receiving comparable access to, or services from, the SEF. The purpose of the proposed impartial access requirements is to prevent a SEF's owners or operators from using discriminatory access requirements as a competitive tool against certain participants. Access to a SEF should be determined, for example, on the SEF's impartial evaluation of an applicant's disciplinary history and financial and operational soundness against objective, pre-established criteria. Any participant should be able to demonstrate financial soundness either by showing that it is a clearing member of a DCO that clears products traded on that SEF or by showing that it has clearing arrangements in place with such a clearing member.

Proposed § 37.202(b) requires that, prior to granting a participant access to its markets, a SEF must require each member or market participant to consent to its jurisdiction.[59] Finally, proposed § 37.202(c) requires a SEF to establish and impartially enforce its rules governing any decision to deny, suspend, or permanently bar participants' access to the SEF, including when such decisions are part of a disciplinary or emergency action taken by the SEF.

Request for Comment:

The Commission solicits specific public comments regarding the sufficiency of proposed § 37.202.

- In particular, the Commission is interested to know whether additional regulations are necessary to ensure that a SEF can assert jurisdiction over any person or entity executing swaps on the SEF, either for their own account or on behalf of another's account.
- The Commission also requests public comments on proposed §§ 37.202(a) and 37.202(c), which are intended to ensure that similarly situated persons and entities receive equal access to a SEF's trading platform and services, and that similar access and services be charged a similar fee.
- In addition, the Commission wants to know whether the proposed regulations seeking to prohibit a SEF from abusing its authority to deny or suspend access via disciplinary or emergency procedures are sufficient to prohibit discrimination by a SEF against competitors or for inappropriate business reasons.

d. Rule Enforcement Program—Proposed § 37.203

Proposed § 37.203 addresses SEF Core Principle 2's requirement that SEFs establish and enforce trading and trade processing rules that will deter abuses and have the capacity to investigate and enforce those rules.[60]

Proposed regulation 37.203(a) addresses abusive trading practices by requiring SEFs to prohibit specific practices in connection with intermediated and non-intermediated trading activities,[61] as well as any other manipulative or disruptive trading practices prohibited by the CEA or by the Commission pursuant to Commission regulation.

Subsection (b) of the proposed regulation requires that a SEF have arrangements and resources for effective rule enforcement, including the authority to collect information and examine books and records of members and market participants. The Commission believes that SEFs must have appropriate resources to enforce all of its rules, including the ability to perform effective trade practice surveillance. Furthermore, a SEF must have the authority to examine books and records for all market participants. The Commission believes that a SEF can best administer its compliance and rule enforcement obligations by having the ability to reach the books and records of all market participants.

Next, subsection (c) of proposed § 37.203 requires that a SEF maintain sufficient compliance resources to conduct effective and timely audit trail reviews, trade practice surveillance, market surveillance, and real-time monitoring. A SEF must also monitor its staff size annually to ensure that it is appropriate to effectively perform those functions. A SEF's staff size also must be sufficient to address unusual or unanticipated market or trading events while continuing to effectively conduct routine self-regulatory duties. Proposed § 37.203 reflects the Commission's belief that sufficient compliance staff are essential to the effectiveness of a SEF's self-regulatory program.

While requiring sufficient staff, proposed § 37.203(c) does not require that staff size be determined based on a specific formula. Rather, it permits the individual SEF to determine what size staff it needs to effectively perform its self-regulatory responsibilities.[62]

Proposed § 37.203(d) requires SEFs to maintain an automated trade surveillance system capable of detecting

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[57] CEA Section 5h(f)(2)(C).

[58] CEA Section 5h(f)(2)(A)(ii) and (2)(B)(i).

[59] Consent may be obtained in the form of a written agreement at the time that a member or market participant is granted access to the SEF.

[60] CEA Section 5h(f)(2)(B).

[61] The prohibited practices include: trading ahead of customer orders, trading against customer orders, accommodation trading, and improper cross-trading. Specific trading practice violations that must be prohibited by all SEFs include: Front-running, wash trading, pre-arranged trading, fraudulent trading, money passes, and any other trading practices that the SEF deems to be abusive. These practices are a compilation of abusive trading practices that DCMs already prohibit, and include trading practices that Congress expressly prohibited in Section 747 of the Dodd-Frank Act. Section 747 of the Dodd-Frank Act amends section 4c(a) of the CEA by adding three disruptive practices, which make it:

Unlawful for any person to engage in any trading, practice, or conduct on or subject to the rules of a registered entity that—

(A) Violates bids or offers;

(B) Demonstrates intentional or reckless disregard for the orderly execution of transactions during the closing period; or

(C) Is of the character of, or is commonly known to the trade as, "spoofing" (bidding or offering with the intent to cancel the bid or offer before execution).

[62] In making this determination, the proposed regulation requires that a SEF take into account specific facts and circumstances (*e.g.,* volume of trading, the number of swaps listed, number of traders, *etc.*), as well as any other factors suggesting the need for increased resources. A factor that may suggest the need for increased compliance resources is a prolonged surge in trading volume or a prolonged period of price volatility.

and investigating potential trade practice violations. At a minimum, a SEF's systems must be capable of generating alerts on at least a trade date plus one day (T+1) basis to help staff focus on potential violations and anomalies found in trade data.[63] They must also provide compliance staff the ability to sort, query and analyze voluminous amounts of data. In order to detect and prosecute the abusive trading practices enumerated in proposed § 37.203(a), a SEF's automated surveillance system must maintain all trade and order data, including order modifications and cancellations. In addition, a SEF's automated trade surveillance system must provide users with the ability to compute retain, and compare trading statistics; compute profit and loss; and reconstruct the sequence of trading activity. The proposed regulation reflects the Commission's belief that a SEF must have automated surveillance systems that are equivalent to those of a DCM in order to fulfill its trade practice surveillance requirements.

Subsection (e) of proposed § 37.203 requires SEFs to conduct real-time market monitoring of all trading activity on its trading platform, in order to ensure orderly trading and to identify and correct any market or system anomalies. The Commission's proposed regulation requires that any price adjustments or trade cancellations be transparent to the market and subject to clear and fair publicly available standards.

Next, proposed § 37.203(f) requires SEFs to establish procedures for conducting investigations and the requirements for an investigation report. Subsection (f)(1) requires that a SEF have procedures to conduct investigations of possible rule violations and subsection (f)(2) requires that an investigation be completed within a timely manner (generally defined as 12 months after an investigation is opened, absent mitigating circumstances).[64]

Subsections (f)(3) and (f)(4) of proposed § 37.203 set forth what must be included in an investigation report. Subsection (f)(3) requires that when compliance staff believes there is a reasonable basis for finding a violation, the investigation report must include the potential wrongdoer's disciplinary history. Similarly, subsection (f)(4) requires that an investigation report include the potential wrongdoer's disciplinary history when compliance staff recommends that a warning letter be issued. The Commission believes that prior disciplinary history is critical information that a disciplinary committee should consider when either issuing a warning letter or assessing an appropriate penalty as part of any settlement decision or hearing.[65]

Subsection (f)(5) of proposed § 37.203 provides that a SEF may authorize its compliance staff to issue a warning letter or to recommend that a disciplinary committee issue a warning letter. However, the proposed regulation prohibits SEFs from issuing more than one warning letter, in lieu of stronger disciplinary action, for the same violation during a rolling 12-month period.[66]

Finally, proposed § 37.203(g) requires a SEF to adopt and enforce any additional rules that it believes are necessary to comply with the requirements of proposed § 37.203.

Request for Comment:

The Commission requests public comment on proposed § 37.203.

- In particular, the Commission requests public comment on the abusive trading practices enumerated in subsection 37.203(a). These practices are identical to the abusive trading practices prohibited in DCM trading.
- The Commission also solicits comments regarding the types of abusive trading practices that should be prohibited on a SEF's trading platform, particularly whether SEFs and DCMs are likely to face similar types of trading abuses by market participants, whether additional or different trading practices should be prohibited on a SEF, and whether SEFs should be required to have the same types of trade practice surveillance and real-time market monitoring programs as DCMs.
- Finally, the Commission requests comments on whether the investigatory reports prepared by DCM compliance staff as a prelude to formal disciplinary proceedings, and included in these proposed regulations, are needed within SEFs.

e. Regulatory Services Provided by a Third Party—Proposed § 37.204

Proposed § 37.204 permits a SEF to utilize the services of a registered futures association or another registered entity for assistance in performing certain self-regulatory functions.[67] However, SEFs remain responsible for the execution of these functions and for compliance with their associated core principles. In this regard, the Commission notes that the Dodd-Frank Act does not confer on SEFs the same right to delegate certain core principle compliance functions as that conferred to DCMs, pursuant to Section 5c(b) of the CEA.

The proposed regulation requires that any SEF that contracts with a third-party regulatory service provider ensure that the provider has sufficient capacity and resources to render timely and effective regulatory services. The SEF must also oversee the quality of regulatory services provided on its behalf, and must retain exclusive authority with respect to all substantive decisions made by its regulatory service provider.[68] The proposed regulation also specifies that any instances where a SEF's actions differ from those recommended by its regulatory provider must be documented and explained in writing.

Request for Comment:

The Commission requests public comment on proposed § 37.204.

- In particular, the Commission requests comments on the supervisory and decision-making relationship that should exist between a SEF and a third-party regulatory service provider.
- The Commission also seeks public comment on the types of information that SEFs and their regulatory service providers should be required to share with other SEFs and regulatory service providers, in order to conduct effective surveillance of fungible swap products trading on multiple SEFs.

[63] These systems typically differ from those systems used for real-time market monitoring. The requirements for real-time market monitoring can be found in proposed Commission § 37.203(e).

[64] Mitigating circumstances may include: the complexity of the investigation, the number of firms or individuals involved as potential wrongdoers, the number of potential violations to be investigated, and the volume of documents and data to be examined and analyzed by compliance staff.

[65] As noted below in the discussion of proposed § 37.206(n), a SEF's disciplinary committee should review a member's complete disciplinary history when determining appropriate sanctions and impose meaningful sanctions on members who repeatedly violate the same or similar rules to discourage recidivist activity.

[66] For purposes of this regulation, the Commission does not consider a "reminder letter" or such other similar letter to be any different than a warning letter. While a warning letter may be appropriate for a first-time violation, the Commission does not believe that more than one warning letter in a rolling 12-month period, whether for the same or similar violations is ever appropriate. A policy of issuing repeated warning letters to members and market participants who violate the same or similar rules, rather than issuing meaningful sanctions, reduces the effectiveness of a SEF's rule enforcement program.

[67] Self-regulatory functions include, for example, trade practice surveillance; market surveillance; real-time market monitoring; investigations of possible rule violations; and disciplinary actions.

[68] Such decisions include, but are not limited to, those involving the cancellation of trades, the issuance of disciplinary charges against members or market participants, denials of access to the trading platform, and any decision to open an investigation into a possible rule violation.

• Finally, because SEFs are not permitted to delegate core principle compliance functions, as are DCMs, are there any additional conditions that the Commission should impose on SEFs' use of third-party regulatory service providers?

f. Audit Trail Requirements—Proposed § 37.205

Proposed § 37.205 addresses SEF Core Principle 2's requirements that a SEF be able to capture information that may be used to determine whether rule violations have occurred.[69] Proposed § 37.205 requirements are akin to the DCM regulations addressing audit trail requirements.[70]

Proposed § 37.205 requires that a SEF establish an audit trail, and sets forth the elements of an effective audit trail and the requirements for effective audit trail enforcement.[71] The Commission believes that these requirements will help to ensure that SEFs can appropriately monitor and investigate any potential customer and market abuse. Additionally, the audit trail data captured by SEFs must be sufficient to reconstruct all transactions promptly, and to provide evidence of any rule violations that may have occurred.

Subsection (b)(1) of the proposed regulation requires that a SEF's audit trail include original source documents, defined to include unalterable, sequentially-identified records on which trade execution information is originally recorded, whether manually or electronically. It also requires that customer order records demonstrate the terms of the order, the unique account identifier that relates to the account owner, and the time of the order entry. Subsection (b)(2) of the proposed regulation requires that a SEF's audit trail program include a transaction history database to facilitate rapid access and analysis of all original source documents. Subsection (b)(2) also specifies the trade information that must be included in a transaction history database.[72] Subsection (b)(3) of the proposed regulation requires that a SEF's audit trail program have electronic analysis capability for all data in its transaction history database and enable the SEF to reconstruct trades in order to identify possible rule violations. Subsection (b)(4) requires that a SEF's audit trail program include the ability to safely store all audit trail data, and to retain it in accordance with the recordkeeping requirements of SEF Core Principle 10 and its associated regulations. Safe storage capability also requires a SEF to protect its audit trail data from unauthorized alteration, accidental erasure or other loss.

Subsection (c) of proposed § 37.205 is organized in two parts. First, subsection (c)(1) requires that a SEF develop an effective audit trail enforcement program, which must, at a minimum, review all members and market participants annually to verify their compliance with all applicable audit trail requirements. Subsection (c)(1) also sets forth minimum review criteria for an electronic trading audit trail that must be carried out by each SEF. Finally, subsection (c)(2) requires that SEFs develop programs to ensure effective enforcement of their audit trail and recordkeeping requirements, including a requirement that SEFs levy meaningful sanctions when deficiencies are found. Sanctions may not include more than one warning letter or other non-financial penalty, in lieu of stronger disciplinary action, for the same violation within a rolling twelve-month period.

Request for Comment:

The Commission seeks public comment on the proposed audit trail and audit trail enforcement requirements for SEFs.

• The Commission seeks specific public comment on whether such requirements should be similar for both SEFs and DCMs.

• Should SEFs be subject to additional requirements beyond the proposed regulations? Are there elements of the proposed regulations that are inappropriate for SEFs?

• For example, is the CTI code system used by DCMs to denote different types of futures participants also necessary for swap transactions on SEFs?

• What specific data points should a SEF's audit trail enforcement program seek to verify?

g. Disciplinary Procedures and Sanctions—Proposed § 37.206

Proposed § 37.206 addresses SEF Core Principle 2's requirement that SEFs establish and enforce participation rules to deter abuse, and have the capacity to investigate and enforce such abuses.[73] Subsection (a) of the proposed regulation requires that a SEF establish and maintain sufficient enforcement staff and resources to effectively and promptly prosecute possible rule violations within the jurisdiction of the SEF. Subsection (a) also provides that a SEF's enforcement staff may not include members of the SEF or persons whose interests conflict with their enforcement duties. Moreover, a member of the enforcement staff may not operate under the direction or control of any person or persons with trading privileges at the SEF. These provisions seek to ensure the independence of enforcement staff, and help promote disciplinary procedures that are free of potential conflicts of interest.

Subsection (b) requires SEFs to establish one or more Review Panels and one or more Hearing Panels (together, "disciplinary panels"). Neither panel may include members of the SEF's compliance staff or any person involved in adjudicating any other stage of the same proceeding.[74] The proposed regulation provides that a Review Panel must be responsible for determining whether a reasonable basis exists for finding a violation of SEF rules, and for authorizing the issuance of a notice of charges, while a separate Hearing Panel must be responsible for adjudicating the matter and issuing sanctions.[75]

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[69] CEA Section 5h(f)(2)(B)(ii).

[70] For further explanation of the elements of an effective audit trail, *see supra* note 10, DCM NPRM.

[71] Subsection (a) of the proposed regulation establishes the overarching requirements for SEFs' audit trail programs, while Subsection (b) prescribes the four elements of an acceptable audit trail program and Subsection (c) prescribes the elements of an effective audit trail enforcement program.

[72] For example, mandatory information includes a history of all orders and trades; all data input in the trade matching system for purposes of clearing; the categories of participant for which each trade is executed (*i.e.,* the customer type indicator or "CTI" codes); timing and sequencing data sufficient to reconstruct trading; and identification of each account to which fills are allocated.

[73] *See* CEA Section 5h(f)(2)(B). In general, the proposed regulations addressing disciplinary procedures for SEFs parallel the disciplinary procedure regulations for DCMs. The proposed regulations pursuant to DCM Core Principle 13 are also similar to the text of the disciplinary procedures in part 8, which the Commission found to be the model for many DCMs' disciplinary programs. 17 CFR 8.01 *et seq.* DCMs were exempt from Part 8 pursuant to § 38.2; however, the predecessor DCM Core Principle 13 offered the disciplinary procedures in Part 8 as an example of appropriate disciplinary procedures.

[74] Disciplinary panels must also adhere to the composition requirement of § 40.9(c)(3)(ii), as proposed, which provides that "Each Disciplinary Panel shall include at least one person who would not be disqualified from serving as a Public Director by § 1.3(ccc)(1)(i)–(vi) and (2) of this chapter (a "Public Participant"). Such Public Participant shall chair each Disciplinary Panel. In addition, any registered entity specified in paragraph (c)(3)(i) of this section shall adopt rules that would, at a minimum: (A) Further preclude any group or class of participants from dominating or exercising disproportionate influence on a Disciplinary Panel and (B) Prohibit any member of a Disciplinary Panel from participating in deliberations or voting on any matter in which the member has a financial interest." *See* 75 FR 63752 (October 18, 2010).

[75] The Commission notes that, while proposed § 37.206(b) requires SEFs to empanel distinct bodies to issue charges and to adjudicate charges in a particular matter, SEFs may determine for themselves whether their Review and Hearing Panels are separate standing panels or ad hoc bodies whose members are chosen from a larger "disciplinary committee" to serve in one capacity or

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Subsection (c) of the proposed regulation requires a Review Panel to promptly review an investigation report received pursuant to proposed § 37.203(f)(3), and to take action within 30 days of receipt. The Commission believes that prompt disciplinary action provides the best opportunity for witnesses to recall conversations, facts, and other information relevant to the matter, and transmits a clear signal to the market and to market participants that violations of exchange rules will not be tolerated. Subsection (c) also specifies the range of actions which a Review Panel may take upon receiving a completed investigation report. Subsection (d) describes the minimally acceptable contents of any notice of charges ("notice") issued by a Review Panel. The notice must adequately state the acts, conduct, or practices in which the respondent is alleged to have engaged; state the rule(s) alleged to have been violated; and prescribe the period within which a hearing may be requested. Further, the notice must advise the respondent charged that he or she is entitled, upon request, to a hearing on the charges.[76] Subsection (e), in turn, specifies a respondent's right to be represented by any counsel or representative of his choosing upon receiving a notice of charges and in all succeeding stages of the disciplinary process. Subsection (f) requires that a respondent must be given a reasonable period of time to file an answer to a charges.[77] Subsection (g) provides that, if a respondent admits or fails to deny any of the alleged violations a Hearing Panel may find that the violations admitted or not denied have been committed.[78] Subsection (h) requires that in every instance where a respondent has requested a hearing on a charge that he or she denies, or on a sanction set by the Hearing Panel pursuant to proposed § 37.206(g), the respondent must be given the opportunity for a hearing in accordance with the requirements of proposed § 37.206(j).

Subsection (i) provides the procedures a SEF must follow when it settles a disciplinary case. The provision states that the rules of a SEF may permit a respondent to submit a written offer of settlement any time after an investigation report is completed. The disciplinary panel presiding over the matter may accept the offer of settlement, but may not alter the terms of the offer unless the respondent agrees. Subsection (i) requires a disciplinary panel that accepts a settlement offer to issue a written decision specifying the rule violations it has reason to believe were committed, and any sanction imposed, including any order of restitution where customer harm has been demonstrated. Significantly, proposed § 37.206(i)(3) also provides that if an offer of settlement is accepted without the agreement of a SEF's enforcement staff, the decision must carefully explain the panel's acceptance of the settlement.[79]

Subsection (j) requires a SEF to adopt rules that provide certain minimum requirements for any hearing conducted pursuant to a notice of charges. In general, Subsections (j)(1)(i) through (j)(1)(vi) require that the SEF: (1) Provide a fair hearing; (2) permit respondents to examine evidence relied on by enforcement staff in presenting the notice of charges; (3) require enforcement and compliance staffs to be parties to the hearing and enforcement staff to present their case on those charges and sanctions that are the subject of the hearing; (4) permit respondents to appear personally at the hearing, to cross-examine and call witnesses and to present evidence; (5) require that persons within its jurisdiction who are called as witnesses participate in the hearing and produce evidence; and (6) transcribe and retain a copy of the hearing. Additionally, subsection (j)(2) specifies that the rules of the SEF may provide that a sanction be summarily imposed upon any person within its jurisdiction whose actions impede the progress of a hearing.

Subsection (k) details the procedures that a Hearing Panel must follow in rendering disciplinary decisions. The provision requires that all decisions include: (1) A notice of charges or a summary of the charges; (2) an answer, if any, or a summary of the answer; (3) a summary of the evidence produced at the hearing or, where appropriate incorporation by reference in the investigation report; (4) a statement of findings and conclusions with respect to each charge, and a careful explanation of the evidentiary and other bases for such findings and conclusions with respect to each charge; (5) an indication of each specific rule which the respondent was found to have violated; and (6) a declaration of any penalty imposed against the respondent, including the basis for such sanctions and the effective date of such sanctions.

Subsection Proposed § 37.206(l) provides the procedures that a SEF must follow in the event that the SEF's rules authorize an appeal of adverse decisions in all or in certain classes of cases.[80] Notably, the proposed § requires a SEF that permits appeals by disciplinary respondents to also permit appeals by its enforcement staff. This provision reflects the Commission's belief that SEF enforcement staff must have the discretion to appeal disciplinary panel decisions that, for example, do not adequately sanction a respondent's violative conduct. Subsection (m) requires that each SEF establish rules setting forth when a decision rendered under this subsection C will become the final decision of the SEF.

Subsection (n) requires that every disciplinary sanction imposed by a SEF must be commensurate with the

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the other for a particular disciplinary matter. The purposes of separate Review and Hearing Panels is to help ensure adjudication of disciplinary matters by separating a decision to issue charges from a hearing on the merits of a matter.

[76] The proposed regulations permit a SEF to adopt rules providing that the failure to request a hearing within the time prescribed in the notice, except for good cause, must be deemed a waiver of the right to a hearing and that the failure to answer or deny expressly a charge must be deemed to be an admission of such charge.

[77] Subsection (f) also permits a SEF, through its rules, to require that: (1) The answer must be in writing and include a statement that the respondent admits, denies or does not have and is unable to obtain sufficient information to admit or deny each allegation; (2) failure to file an answer on a timely basis shall be deemed an admission of all allegations in the notice of charges; and (3) failure in an answer to deny expressly a charge shall be deemed to be an admission of such charge.

[78] In addition, if a SEF adopts a rule concerning the admission or failure to deny charges pursuant to Proposed § 37.206(f), then Subsections (g)(1) through (g)(3) of the proposed regulation provide that: (1) The Hearing Panel must impose a sanction for each violation found to have been committed; (2) the SEF must promptly notify the respondent in writing of any sanction to be imposed and advise the respondent that they may request a hearing on such sanction within the period of time stated in the notice; and (3) the rules of the SEF may provide that if the respondent fails to request a hearing within the period of time stated in the notice, then the respondent will be deemed to have accepted the sanction.

[79] Subsection (i) allows a respondent to withdraw his or her offer of settlement at any time before final acceptance by a disciplinary panel. If an offer is withdrawn after submission, or is rejected by a disciplinary panel, the respondent must not be deemed to have made any admissions by reason of the offer of settlement and must not be otherwise prejudiced by having submitted the offer of settlement.

[80] For SEFs that permit appeals, the language in subsections (l)(1) through (l)(4) of proposed § 37.206 generally require the SEF to: (1) Establish an appellate panel that is authorized to hear appeals; (2) ensure that the appellate panel composition is consistent with § 40.9(c)(3)(iii) and not include any members of the SEF's compliance staff, or any person involved in adjudicating any other stage of the same proceeding; (3) except for good cause shown, the appeal or review must be conducted solely on the record before the Hearing Panel, the written exceptions field by the parties, and the oral or written arguments of the parties; and (4) promptly following the appeal or review proceeding, the board of appeals must issue a written decision and provide a copy to the respondent. The Commission notes that a respondent has certain rights of appeal to the Commission under Part 9 of the Commission's regulations.

violations committed and must be clearly sufficient to deter recidivism or similar violations by other market participants. Additionally, the proposed regulation requires that, in the event of demonstrated customer harm, any disciplinary sanction must include full customer restitution. In evaluating appropriate sanctions, the proposed regulation requires the SEF to take into account a respondent's disciplinary history.[81]

Subsection (o) permits a SEF to adopt a summary fine schedule for violations of rules relating to timely submission of accurate records required for clearing or verifying each day's transactions. The proposed regulation makes clear that a SEF should issue no more than one warning letter in a rolling 12-month period for the same violation before sanctions are imposed. Additionally, the proposed regulation specifies that a summary fine schedule must provide for progressively larger fines for recurring violations. The Commission believes that these provisions will serve to discourage recidivist behavior.

Finally, subsection (p) provides that a SEF may impose an immediate sanction upon a reasonable belief that such action is necessary to protect the best interest of the marketplace. The proposed regulation also provides that any emergency action taken by the SEF must be performed in accordance with certain procedural safeguards.

Request for Comment:

The Commission seeks public comment on proposed § 37.206.

- In particular, comments should address whether SEFs should be subject to the detailed disciplinary procedures proposed herein. The proposed disciplinary procedures emphasize procedural safeguards for respondents, including a clear separation between SEF personnel recommending the issuance of charges, review panels determining whether charges should be issued, and hearing panels adjudicating cases on the merits. Are these disciplinary procedures sufficient for SEFs? Or, should SEFs instead utilize a more streamlined disciplinary process that features, for example, a robust staff summary fine program rather than formal disciplinary hearings.
- Finally, given the significant financial resources of the ECPs conducting swap transactions on SEFs, should Commission regulations provide more detailed guidelines on the appropriate size of any financial penalties levied by SEFs for violative conduct? Should any such guidelines take cognizance of the financial resources of potential respondents?

h. Swaps Subject to Mandatory Clearing—Proposed § 37.207

Proposed § 37.207 mandates that SEFs provide rules that require swap dealers or major swap participants, who trade a swap subject to the mandatory clearing requirement under Section 2(h)(1), to execute the transaction on either a DCM or a SEF. However, swap dealers or major swap participants are not required to execute such transactions if no DCM or SEF makes the swap available to trade.

3. Subpart D—Core Principle 3 (Swaps Not Readily Susceptible to Manipulation)

Under Core Principle 3, Congress required that SEFs offer for trading swaps that are not readily susceptible to manipulation. The Commission notes that the statutory language of Core Principle 3 is substantively identical to the counterpart core principle under Section 5(d)(3) of the CEA as applicable to DCMs. Historically, DCMs complied with the requirements of Section 5(d)(3) by using as guidance the provisions of Guideline No. 1, contained in Appendix A to Part 40. In a separate release, the Commission proposes certain revisions to the former Guideline No. 1, including: (i) Amending the provisions to include swap transactions, (ii) re-titling the guidance as "Demonstration of compliance that a contract is not readily susceptible to manipulation," and (iii) re-designating the guidance to be included under Appendix C to Part 38.[82]

Accordingly, proposed § 37.301 requires that, applicants and SEFs must provide to the Commission the information required under Appendix C to Part 38 for purposes of demonstrating to the Commission that their swap contracts are not readily susceptible to manipulation.

Under Appendix B to Part 37, the guidance for compliance with Core Principle 3 focuses on the selection and construction of the price index on which the swaps' cash flows are based. If obtained from a private third-party, the company should be independent and reputable. Moreover, the third party should use a sound, well-documented methodology that protects the index from manipulation. If the SEF itself determines the price index, then it should take precautions to safeguard against attempts to artificially influence the index. In this regard, if the price index is based on a survey of cash market sources, then the SEF should maintain a list of such entities which all should be reputable sources with knowledge of the cash market. In addition, the sample of sources polled should be representative of the cash market, and the poll should be conducted at a time when trading in the cash market is active. The cash-settlement survey should include a minimum of four independent entities if such sources do not take positions in the commodity (*e.g.,* if the survey list is comprised exclusively of brokers) or at least eight independent entities if such sources trade for their own accounts (*e.g.,* if the survey list is comprised of dealers or commercial users).

4. Subpart E—Core Principle 4 (Monitoring of Trading and Trade Processing)

Under Core Principle 4, Congress required that SEFs must take an active role in preventing manipulation, price distortion and disruptions of the delivery or cash settlement process. Accordingly, the proposed regulations under Subpart E of Part 37 clarify the related responsibilities for applicants and SEFs to monitor trading activities and prevent market disruptions.

a. General Requirements—Proposed § 37.401

Proposed § 37.401 requires that applicants and SEFs must collect, monitor and evaluate data to detect and prevent manipulative activity. Proposed § 37.401 also requires that applicants and SEFs have the ability to conduct real-time monitoring of trading and comprehensive and accurate trade reconstructions.

As noted above in its discussion of the need for automated tools in connection with Core Principle 2 requirements, the Commission believes that it would be difficult, if not impossible, to monitor for market disruptions in markets with high transaction volume and a large number of trades unless the SEF has installed automated trading alerts to detect many types of potential violations of exchange or Commission rules. Accordingly, the Commission proposes in § 37.401 to require that, where the SEF cannot reasonably demonstrate that its manual processes are effective in detecting and preventing abuses, the SEF must implement automated trading alerts to detect potential problems.

[81] Proposed § 37.203(f)(3) also requires that a copy of a member or market participant's disciplinary history be included in the compliance staff's investigation report.

[82] *See, supra* note 10, DCM NPRM.

Request for Comment:

The Commission seeks public comment on whether in any rule the Commission may adopt in this matter, SEFs should be required to monitor the extent of high frequency trading, and whether automated trading systems should include the ability to detect and flag high frequency trading anomalies.

b. Additional Requirements for Physical-Delivery Swaps—Proposed § 37.402

For physical delivery swaps, proposed § 37.402 requires that SEFs monitor each swap's terms and conditions as well as take meaningful corrective action to allow market participants to continue to use the market to make sound hedging decisions and for price discovery.

c. Additional Requirements for Cash-Settled Swaps—Proposed § 37.403

Over the past several years, there has been a growth in markets that are linked, for example, where the settlement price of one market is linked to the prices established in another market. As a result, traders may have incentives to disrupt or manipulate prices in the reference market in order to influence the prices in the linked market. The Commission believes that in such situations SEFs must monitor trading in the market to which its swap is linked. Accordingly, proposed § 37.403 requires that, where a swap is settled by reference to the price of an instrument traded in another venue the SEF must either have an information sharing agreement with the other venue or be able to independently determine that positions or trading in the reference instrument are not being manipulated to affect positions or trading in its swap.

d. Ability To Obtain Information—Proposed § 37.404

To ensure that SEFs have the ability to properly assess the potential for price manipulation, price distortions, and the disruption of the delivery or cash-settlement process, proposed § 37.404 provides that SEFs require that traders in their market keep and make available records of their activity in underlying commodities and related derivatives markets and swaps.

e. Risk Controls for Trading—Proposed § 37.405

Proposed § 37.405 requires that a SEF have effective risk controls to reduce the potential risk of market disruptions and ensure orderly market conditions. In the current futures markets, DCMs have implemented a variety of risk controls to avoid market disruptions through restrictions on order entry, including daily price limits, price/quantity bands, and trading pauses. In order to prevent market disruptions due to sudden volatile price movements, proposed § 37.405 requires SEFs to have in place effective risk controls, including but not limited to pauses and/or halts to trading in the event of extraordinary price movements that may result in distorted prices or trigger market disruptions. Such risk controls can, among other things, allow time for participants to analyze the market impact of new information that may have caused a sudden market move, allow new orders to come into a market that has moved dramatically, and allow traders to assess and secure their capital needs in the face of potential margin calls. Moreover, where a swap is linked to, or a substitute for, other swaps on the SEF or other trading venues, including where a swap is based on the level of an equity index, risk controls should be coordinated with those on the similar markets or trading venues, to the extent possible.

The desirability of coordination of various risk controls, for example, "circuit breakers" in equities and their various derivatives including futures and options, recently has been the subject of discussions by regulators and the industry. The Commission believes that pauses and halts are effective risk management tools and must be implemented by SEFs to facilitate orderly markets. These basic risk controls also have proven to be effective and necessary in preventing market disruptions. The Commission recognizes that pauses and halts are only one category of risk controls and that additional controls may be necessary to further reduce the potential for market disruptions. Such controls may include price collars or bands,[83] maximum order size limits,[84] stop loss order protections,[85] kill buttons,[86] and others.

[83] Price bands would prevent clearly erroneous orders from entering the trading system, including "fat finger" errors, by automatically rejecting orders priced outside of a range of reasonability.

[84] Maximum order size limitations would prevent entry into the trading system of an order that exceeds a maximum quantity established by the SEF.

[85] Stop loss orders would be triggered if the market declines to a level pre-selected by the person entering the order. This mechanism would provide that when the market declines to the trader's pre-selected stop level for such an order, the order would become a limit order executable only down to a price within the range of reasonability permitted by the system, instead of becoming a market order.

[86] Kill buttons would give clearinghouses associated with a SEF the ability to delete open orders and quotes and reject entry of new orders or quotes in instances where a trader breaches its obligations with the clearinghouse. *See* FIA Market Access Risk Management Recommendations, p. 10 (April 2010).

Request for Comment:

The Commission is considering mandating in this rulemaking risk controls that are appropriate and/or necessary. Accordingly, the Commission invites comments on the appropriateness of these and other controls that could supplement trading halts or pauses. The Commission also invites comments on the following additional questions:

- Which risk controls should be mandated and how?
- What types of pauses and halts are necessary and appropriate for particular market conditions?
- What other risk controls are appropriate or necessary to reduce the risk of market disruptions?

f. Trade Reconstruction—Proposed § 37.406

Under Core Principle 4, Congress required that SEFs have the ability to comprehensively and accurately reconstruct all trading on its facility. Proposed § 37.406 sets forth this requirement, including the requirement that audit-trail data and reconstructions be made available to the Commission upon request.

g. Additional Rules Required—Proposed § 37.407

Proposed § 37.407 requires SEFs to adopt and enforce any additional rules that it believes are necessary to comply with the requirements of Subpart E.

5. Subpart F—Core Principle 5 (Ability To Obtain Information)

The proposed regulations under Subpart F require an applicant and a SEF to have the ability and authority, necessary Core Principle 5, to obtain necessary information to perform its obligations.

6. Subpart G—Core Principle 6 (Position Limits or Accountability)

Under Core Principle 6, Congress required that SEFs adopt for each swap, as is necessary and appropriate, position limits or position accountability. In addition, Congress required that, for any contract that is subject to a Federal position limit under CEA Section 4a(a), the SEF shall set its position limits at a level no higher than the position limitation established by the Commission in its Part 151 regulations. Proposed § 37.601 requires that each SEF must comply with the requirements of Part 151 in order to be in compliance with Core Principle 6.

7. Subpart H—Core Principle 7 (Financial Integrity of Transactions)

Proposed § 37.700 sets out the financial integrity requirements for transactions on a SEF, as required under Core Principle 7. Under such core principle, a SEF must establish and enforce rules to ensure the financial integrity of swaps entered on or through the facilities of the SEF, including the clearing and settlement of the swaps. The requirements of proposed § 37.700 depend, in part, on whether the swap is cleared.[87]

Under proposed § 37.702(a), a SEF must ensure that all its members meet the definition of "eligible contract participant" under CEA Section 1(a)(18). Under proposed § 37.702(b), for swaps cleared by a DCO, a SEF must ensure that it has the capacity to route transactions to the DCO. With respect to swaps that are not required to be cleared, a SEF must impose additional requirements to ensure the financial integrity of the transaction,[88] including requiring the transacting member to have entered into a credit arrangement for the transaction, demonstrate an ability to exchange collateral, and have appropriate credit filters in place. The Commission believes that these additional requirements are necessary in light of the fact that uncleared swaps will not have the risk management protections of a DCO.

The Commission requests comment on whether these standards are appropriate financial integrity safeguards for SEFs. Specifically, the Commission solicits comment regarding how SEF members would demonstrate sufficient credit documentation and ability to exchange collateral.

Request for Comment:

The Commission seeks public comment on the proposed rule, and specifically on the following questions:

- Whether SEFs should provide additional controls to permit FCMs to manage their risks? If so, what specific direct access controls and procedures should SEFs implement?
- Should such controls be mandatory?

[87] The Commission interprets the mandatory clearing requirement in Section 723(a)(3) of the Dodd-Frank Act to mean that a DCO must clear a swap for any DCM or SEF that requests such clearing services, so long as the DCO offers the swap. In addition, a DCO that is clearing particular swaps must also clear the same swaps when listed on DCMs or SEFs, whether affiliated or unaffiliated, on a nondiscriminatory basis.

[88] Separately, if the SEF determines to allow swap transactions that are not cleared, the SEF must have provisions to determine that the swap meets the exemption to the clearing requirement provided under section 2(h)(7) of the CEA, as amended by the Dodd-Frank Act.

8. Subpart I—Core Principle 8 (Emergency Authority)

Under Core Principle 8, a SEF must provide for emergency situations. Based upon its experience with DCMs, and in recognition of the fact that individual SEFs may have different approaches to handling emergency action, proposed § 37.801 refers to the guidance in Appendix B to Part 37 to demonstrate compliance with Core Principle 8.

The guidance reflects the Commission's belief that there should be an increased emphasis on cross-market coordination of emergency actions and SEFs should have alternate lines of communication and approval procedures in order to address emergencies in real time.

The Commission's experience has demonstrated that there are some specific requirements that at a minimum should be followed and these requirements are incorporated under the proposed guidance. Specifically, the SEF should have procedures and guidelines for decision-making and implementation of emergency intervention in the market. The SEF should have the authority to perform various actions, including without limitation: Liquidating or transferring open positions in the market,[89] suspending or curtailing trading in any swap, and taking such market actions as the Commission may direct. In addition, the guidance notes that SEFs must provide prompt notification and explanation to the Commission of the exercise of emergency authority, and that information on all regulatory actions carried out pursuant to a SEF's emergency authority should be included in a timely submission of a certified rule.

9. Subpart J—Core Principle 9 (Timely Publication of Trading Information)

Under Core Principle 9, Congress required that SEFs make available to the public timely information on price, trading volume, and other trading data on swaps to the extent prescribed by the Commission. Congress also required a SEF to have the capability of electronically capturing trade information for those transactions that occur on the trading system or platform. These matters are addressed in separate releases.[90] Proposed § 37.901 requires that SEFs comply with the real-time swap reporting and swap reporting and recordkeeping requirements being separately proposed by the Commission.

[89] In situations where a swap is traded on more than one platform, emergency action to liquidate or transfer open interest must be directed, or agreed to, by the Commission or Commission staff.

[90] *See, supra* note 10, DCM NPRM; 75 FR 76140 (December 7, 2010); and 75 FR 76574 (December 8, 2010).

Request for Comment:

In order to address all relevant considerations with respect to the reporting requirements of Core Principle 9, the Commission seeks general comments and asks the public to respond to the specific questions below.

- For interest rate swaps, because the term life on an interest rate swap can be one of a large number of possible periods along a yield curve, what would be an appropriate manner to display prices?
- Would prices for interest rate swaps be meaningful or misleading and why?
- If the prices are misleading, what useful information should be displayed at the end of the trading day?
- Please identify any other swap products that have similar price reporting issues and address how the prices for that product should be reported to provide a summary of the trading for that day.

10. Subpart K—Core Principle 10 (Recordkeeping and Reporting)

Core Principle 10 establishes a three-part recordkeeping and reporting requirement applicable to all SEFs, which the Commission proposes to implement through proposed §§ 37.1001–37.1003.[91]

Proposed § 37.1001 largely codifies the statutory language of Core Principle 10. In addition, it clarifies that investigatory and disciplinary files are included in the records that a SEF must maintain, and requires that a SEF comply with the recordkeeping requirements of § 1.31.[92]

By incorporating § 1.31, proposed § 37.1001 effectively requires that SEF books and records be readily accessible for the first 2 years of the minimum 5-

[91] CEA Section 5h(f)(10)(A) requires all SEFs to: Maintain records of all activities relating to the business of each SEF, including a complete audit trail, for a period of at least five years; report to the Commission, in a form and manner acceptable to the Commission, such information as the Commission determines to be necessary or appropriate; and keep records relating to swaps defined in CEA Section 1a(47)(A)(v) open to inspection and examination by the Securities and Exchange Commission. CEA Section 5h(f)(10)(B) requires the Commission to "adopt data collection and reporting requirements for swap execution facilities that are comparable to corresponding requirements for derivatives clearing organizations and swap data repositories." The Commission's data standards are included in proposed rules in Part 45 of the Commission's regulations.

[92] The Commission notes that it has always considered audit trails and investigatory and disciplinary files as a part of the records which a DCM is required to maintain and which the Commission is permitted to request and to examine. In this respect, the proposed regulation merely codifies existing Commission practice.

year statutory period and be open to inspection by any representatives of the Commission or the United States Department of Justice.[93] The SEF, at its own expense, must promptly provide either a copy or the original books or records upon request.

The statutory regime for SEFs established by the Dodd-Frank Act envisions ongoing Commission oversight of SEFs and their trading activity. Such oversight will resemble, in concept, the oversight already conducted by the Commission with respect to DCMs. Accordingly, proposed § 37.1002 requires that SEFs report to the Commission any information necessary or appropriate for the Commission to perform its oversight duties. The proposed regulation does not articulate specific information that must be provided to the Commission; instead, it establishes the general requirement that SEFs must provide any relevant data requested by the Commission in a form and manner acceptable to the Commission.[94]

Proposed § 37.1003 codifies Core Principle 10's statutory requirement that a SEF keep any records relating to security-based swap agreements defined in Section 1a(47)(A)(v) of the CEA open to inspection and examination by the Securities and Exchange Commission ("SEC").[95]

11. Subpart L—Core Principle 11 (Antitrust Considerations)

Core Principle 11 governs the antitrust obligations of SEFs.[96] This SEF core principle is substantially similar to DCM Core Principle 19.[97] The Commission believes that the existing guidance applicable to DCM Core Principle 19 remains appropriate. Accordingly, the Commission proposes to codify the statutory text of Core Principle 11 into proposed § 37.1100. Additionally, proposed § 37.1101 refers applicants and SEFs to the guidance in Appendix B to Part 37 for purposes of demonstrating compliance with proposed § 37.1100.

12. Subpart M—Core Principle 12 (Conflicts of Interest)

Core Principle 12 governs conflicts of interest. Like Core Principle 11, Core Principle 12 is substantially similar to both the DCM and the DCO conflicts of interest core principles, as amended by the Dodd-Frank Act.[98] As a result, the Commission proposes to handle Core Principle 12 consistent with its handling of those DCM and DCO core principles. This release proposes to codify the statutory text of the core principle in proposed § 37.1200. The applicable regulations implementing this core principle were proposed in a separate release titled "Requirements for Derivatives Clearing Organizations, Designated Contract Markets, and Swap Execution Facilities Regarding the Mitigation of Conflicts of Interest."[99]

13. Subpart N—Core Principle 13 (Financial Resources)

Core Principle 13 requires that a SEF have adequate financial resources to discharge its responsibilities. In particular, SEFs must maintain financial resources sufficient to cover operating costs for a period of at least one year, calculated on a rolling basis.

a. General Rule

Under proposed § 37.1301(b), SEFs that also operate as DCOs are also subject to the financial resource requirements for DCOs in proposed § 39.11. Proposed § 37.1301(c) would require that SEFs maintain sufficient financial resources to cover operating costs for at least one year, calculated on a rolling basis—*i.e.,* at all times. The one year period is required under the CEA. The Commission believes that a one-year timeframe would allow a SEF's business to wind down in an orderly fashion and should generally enhance the financial integrity of the markets.[100]

The one-year period also is consistent with established accounting standards, under which an entity's ability to continue as a going concern comes into question if there is evidence that the entity may be unable to continue to meet its obligations in the next 12 months without substantial disposition of assets outside the ordinary course of business, restructuring of debt, externally forced revisions of its operations, or similar actions.[101]

b. Types of Financial Resources

Under proposed § 37.1302, financial resources available to SEFs to satisfy the applicable financial requirements would include the SEF's own capital (assets in excess of liabilities) and any other financial resource deemed acceptable by the Commission. A SEF would be able to request an informal interpretation from CFTC staff on whether or not a particular financial resource would be acceptable.

Request for Comment:

The Commission invites commenters to recommend particular financial resources for inclusion in the final regulation.

c. Computation of Financial Resource Requirement

Proposed § 37.1303 would require that a SEF, at the end of each fiscal quarter, make a reasonable calculation of the financial resources it needs to meet the requirements of proposed

[93] Proposed § 37.1001 also effectively incorporates § 1.31(b)'s description of the permissible methods of storing books and records. Consequently, a SEF may store its books and records as prescribed by § 1.31(b)(1)(ii). Among other criteria, § 1.31(b)(1)(ii) defines electronic storage media as "any digital storage medium or system that preserves the records exclusively in a non-rewritable, non-erasable format [and] verifies automatically the quality and accuracy of the storage media recording process * * *." SEFs must, at all times, have the facilities to immediately produce and be prepared to present legible hard-copy images of such records. Additionally, SEF's must keep only Commission-required records on the media, store a duplicate of the record at a separate location, and organize and maintain an accurate index of all information maintained on both the original and duplicate storage media. SEFs that use electronic storage media are also required to develop and maintain an audit system to track the initial entry of original or duplicate records and any subsequent changes made thereafter. Proposed § 37.1001 also incorporates §§ 1.31(c) and 1.31(d), which expand upon the requirements established by proposed § 37.1001. Section 1.31(c) requires that record-keepers who employ an electronic storage system certify with Commission that the system meets the requirements of an electronic storage media as defined in § 1.31(b)(1)(ii). Section 1.31(d) states that trading cards, documents on which trade information is originally recorded in writing, certain written orders, and paper copies of certain electronically filed forms and reports with original signatures must be retained in hard-copy for the requisite time period. Finally, proposed § 37.1001 also requires that SEFs comply with the recordkeeping requirements applicable to swaps in proposed Part 45.

[94] The Commission anticipates that the records it will routinely request will include, for example, daily trading records, board of directors' meeting minutes, investigatory and disciplinary files, information regarding resources allocated to compliance functions, and other records used in the Commission's trade practice surveillance program and rule enforcement review program.

[95] CEA Section 5h(f)(10)(A)(iii).

[96] Part 38 contains guidance governing compliance with former Core Principle 18. 17 CFR part 38, App. B.

[97] Prior to the Dodd-Frank Act, the DCM core principle on antitrust considerations was numbered as DCM Core Principle 18.

[98] DCM Core Principle 16 and DCO Core Principle P, both as amended by the Dodd-Frank Act.

[99] 75 FR 63732 (October 18, 2010).

[100] Some foreign regulatory authorities already have similar requirements for the equivalent entities they regulate. For example, the UK Financial Services Authority's ("FSA") recognition requirements for UK recognized investment exchanges and UK recognized clearing houses (collectively, "UK recognized bodies") include the maintenance of financial resources sufficient to ensure that the UK recognized body would be able to complete an orderly closure or transfer of its business without being prevented from doing so by insolvency or lack of available funds. Section 2.3.7 of the FSA Recognition Requirements calls for a UK recognized body to have at all times liquid financial assets amounting to at least six months' operating costs and net capital of at least that amount.

[101] *See* American Institute of Certified Public Accountants Auditing Standards Board Statement of Auditing Standards No. 59, The Auditor's Consideration of an Entity's Ability to Continue as a Going Concern, as amended.

§ 37.1301. In the first instance, the SEF would have reasonable discretion in determining how to make this calculation, the Commission may require changes as appropriate.

d. Valuation of Financial Resources

Proposed § 37.1304 would require that SEFs, no less frequently than quarterly, calculate the current market value of each financial resource used to meet their obligations under these proposed regulations. Additionally, SEFs would have to perform the valuation at other times as appropriate. This provision is designed to address the need to update valuations in circumstances where there may have been material fluctuations in market value that could impact a SEF's ability to meet its obligations under proposed § 37.1301. When valuing a financial resource, a SEF would be required to reduce the value, as appropriate, to reflect any market or credit risk specific to that particular resource, *i.e.,* apply a haircut.[102]

e. Liquidity of Financial Resources

Proposed § 37.1305 would require that SEFs maintain unencumbered liquid financial assets, such as cash or highly liquid securities, equal to at least six months' operating costs. The Commission believes that having six months' worth of unencumbered liquid financial assets would give a SEF time to liquidate the remaining financial assets it would need to continue operating for the last six months of the required one-year period. If a SEF does not have six months' worth of unencumbered liquid financial assets, it would be allowed to use a committed line of credit or similar facility to satisfy this requirement.

The Commission notes that a committed line of credit or similar facility is not listed in proposed § 37.1302 as a financial resource available to a SEF to satisfy the requirements of proposed § 37.1301. A SEF may only use such resources to meet the liquidity requirements of proposed § 37.1305.

f. Reporting Requirements

Under proposed § 37.1306, at the end of each fiscal quarter, or at any time upon Commission request, SEFs would be required to report to the Commission: (i) The amount of financial resources necessary to meet the requirements set forth in the regulation; and (ii) the value of each financial resource available to meet those requirements. A SEF would also have to provide the Commission with a financial statement, including the balance sheet, income statement, and statement of cash flows, of the SEF or of its parent company, as appropriate.

14. Subpart O—Core Principle 14 (System Safeguards)

Core Principle 14 requires that SEFs: (1) Establish and maintain a program of risk oversight to identify and minimize sources of operational risk through the development of appropriate controls and procedures and the development of automated systems that are reliable, secure, and have adequate scalable capacity; (2) establish and maintain emergency procedures, backup facilities, and a plan for disaster recovery that allow for the timely recovery and resumption of operations; and (3) periodically conduct tests to verify that backup resources are sufficient to ensure continued order processing and trade matching, price reporting, market surveillance, and maintenance of a comprehensive and accurate audit trail. Proposed § 37.1401 would establish system safeguards requirements for all SEFs, pursuant to Core Principle 14.

The proposed rule would require that a SEF's program of risk analysis and oversight address six categories of risk analysis and oversight, including: Information security; business continuity-disaster recovery ("BC–DR") planning and resources, capacity and performance planning; systems operations; systems development and quality assurance; and physical security and environmental controls.

Because automated systems play a central and critical role in today's electronic financial market environment, oversight of core principle compliance by SEFs with respect to automated systems is an essential part of effective oversight of the trading of swaps. Sophisticated computer systems will be crucial to a SEF's ability to meet its obligations and responsibilities. SEF compliance with generally accepted standards and best practices with respect to the development, operation, reliability, security and capacity of automated systems can reduce the frequency and severity of automated system security breaches or functional failures, thereby augmenting efforts to mitigate systemic risk.

15. Subpart P—Core Principle 15 (Designation of Chief Compliance Officer)

Section 5h(f)(15) of the CEA, as added by Section 733 of the Dodd-Frank Act, creates an internal regulatory framework for all SEFs, with the position of chief compliance officer ("CCO") serving as a focal point for compliance with the CEA and applicable Commission regulations. The four-part structure of Section 5h(f)(15) requires, first, that every SEF designate an individual to serve as CCO. Second, it enumerates specific duties for CCOs and establishes their responsibilities within a SEF. Third, it requires CCOs to design the procedures establishing the handling, management response, remediation, retesting, and closing of noncompliance issues. Fourth, it outlines the requirements of a mandatory annual report from SEFs to the Commission, which must be prepared and signed by a SEF's CCO. The Commission proposes to implement Section 5h(f)(15) of the CEA through proposed § 37.1501, which further develops the already robust CCO requirements enacted by the Dodd-Frank Act. Section 5h(f)(15) of the CEA and proposed § 37.1501 are summarized below.

The first provision of Section 5h(f)(15)–5h(f)(15)(A)—provides only for the self-explanatory requirement that each SEF designate an individual to serve as its CCO. The second provision of Section 5h(f)(15) offers a detailed description of a CCO's role within a SEF. Specifically, Section 5h(f)(15)(B) includes six enumerated duties incumbent upon all CCOs, and thereby outlines the internal regulatory structure of a SEF as contemplated by the Dodd-Frank Act. The enumerated duties of CCOs include: (1) Reporting directly to the SEF's board of directors or to its senior officer; (2) reviewing an SEF's compliance with the requirements and core principles described in Section 5h; (3) resolving any conflicts of interest that may arise, in consultation with the board of directors or the senior officer of the SEF; (4) establishing and administering any policy or procedure that is required to be established by a SEF pursuant to Section 5h; (5) ensuring compliance with the CEA, including rules prescribed by the Commission pursuant to Section 5h; and (6) establishing procedures for the remediation of noncompliance issues identified by the CCO. The third provision of Section 5h(f)(15) provides that the CCO in establishing and following appropriate procedures shall design such procedures for the handling, management response, remediation, retesting, and closing of noncompliance issues.

Finally, the fourth provision of Section 5h(f)(15)–5h(f)(15)(D)—requires CCOs to prepare and sign annual compliance reports on behalf of their

[102] The Commission would permit each SEF to exercise its discretion in determining the applicable haircuts. However, such haircuts are subject to Commission review and must be acceptable to the Commission.

SEFs. The annual compliance reports must describe a SEF's compliance with the CEA and Commission regulations. They must also describe the policies and procedures of the SEF, including the code of ethics and conflict of interest policies. In addition, the annual compliance reports must include "a certification that, under penalty of law, the report is accurate and complete." The annual compliance report must be furnished to the Commission as it may prescribe.

Proposed subpart P develops each of these statutory provisions in greater detail and grants CCOs the regulatory authority necessary to fulfill responsibilities in each regard.

a. Definition of Board of Directors—Proposed § 37.1501(a)

Proposed § 37.1501(a) defines "board of directors" as "the board of directors of a swap execution facility or for those swap execution facilities whose organizational structure does not include a board of directors, a body performing a function similar to a board of directors." The proposed definition reflects the various forms of business associations which a SEF could conceivably take, including forms which do not include a corporate board of directors. It also reflects the flexibility in Section 733 of the Dodd-Frank Act, which refers, for example, to "a body performing a function similar to a board" in discussing the duties of a CCO pursuant to Section 5h(f)(15)(B)(iii) of the CEA.

Request for Comment:

The Commission requests comment on the following:

- Should the Commission develop additional rules around the types of bodies which may perform board-like functions at a SEF, depending on their business form?
- Should the proposed definition of board of directors appropriately address issues related to parent companies, subsidiaries, affiliates, and SEFs located in foreign jurisdictions? Does the proposed rule allow for sufficient flexibility with regard to a SEF's business structure?

b. Designation and Qualifications of Chief Compliance Officer—Proposed § 37.1501(b)

Proposed § 37.1501(b)(1) requires a SEF to establish the position of CCO, designate an individual to serve in that capacity and provide that individual with the authority and resources to develop and enforce policies and procedures necessary to fulfill the duties set forth for CCOs in the Dodd-Frank Act and Commission regulations. In addition, proposed § 37.1501(b)(1) provides that CCOs must have supervisory authority over all staff acting in furtherance of the CCO's statutory and regulatory obligations. In short, proposed § 37.1501(b)(1) establishes CCOs as the focal point of a SEF's regulatory compliance functions.

Proposed § 37.1501(b)(2) details minimum competency standards for CCOs. It requires that CCOs have the background and skills necessary to fulfill the responsibilities of the position, and prohibits anyone who would be disqualified from registration under Sections 8a(2) or 8a(3) of the CEA from serving as a CCO. Although the CCO would not be required to register with the Commission, as the primary individual with responsibility for ensuring a SEF's legal compliance, the Commission believes that CCOs should meet the same standard as those individuals who are required to register, as set forth in the list of statutory disqualifications under Sections 8a(2) and (3) of the CEA. These standards largely consist of a high degree of responsibility and requirements relating to integrity and honesty in financial and business dealings. Section 37.1501(b)(2) also requires that a CCO not serve as general counsel of a SEF. This prohibition reflects the Commission's belief that granting these dual roles to a single individual is incompatible with effective regulation and self-regulation.[103]

Request for Comment:

The Commission is seeking comment on whether additional limitations should be placed on persons who may be designated as a CCO.

- The Commission requests comment on whether the provisions of proposed § 37.1501(b) are sufficient to ensure that a CCO has the authority and resources necessary to fulfill his or her statutory and regulatory obligations.
- The Commission also requests comment regarding the qualifications that should be required of a CCO, and whether the requirements expressed in proposed § 37.1501(b) are sufficient.
- Should there be additional restrictions placed on who is qualified to be designated as a CCO? The Commission requests comment on whether restricting a CCO from serving as the General Counsel or other attorney within the legal department of a SEF would sufficiently address conflict of interest concerns?

c. Appointment, Supervision, and Removal of Chief Compliance Officer—Proposed § 37.1501(c)

Taken together, proposed §§ 37.1501(c)(1), 37.1501(c)(2), and 37.1501(c)(3) provide the supervisory regime applicable to CCOs. Proposed § 37.1501(c) requires that a CCO be appointed by a majority of the SEF's board of directors or senior officer, and that a majority of the board or senior officer be responsible for approving the CCO's compensation. A SEF must notify the Commission within two business days of appointing a new CCO. The proposed regulation also requires the CCO to meet at least annually with the board of directors to discuss the effectiveness of the CCO's administration of the compliance policies adopted by the registrant. The meeting or meetings would create an opportunity for a CCO and the directors to speak freely about any sensitive issues of concern to any of them, including any reservations about the cooperativeness or compliance practices of the registrant's management. The Commission's governance proposals require that each SEF's board of directors include a board-level regulatory oversight committee ("ROC") consisting exclusively of public directors.[104] The Commission believes

[103] As conceived by the Commission, SEF CCOs have overall responsibility for SEFs' compliance programs. CCOs must be neutral fact-finders, and must be able to act in the interest of effective compliance regardless of the persons, entities, or conduct that may be the subject of investigation. In contrast, an entity's general counsel serves as the legal counsel and defender of a company and seeks to avoid or negate related legal risks. A second basis for the separation of the general counsel and CCO roles is the Commission's determination that an individual acting as CCO should not be in a position to assert attorney-client privilege against the Commission. If a SEF's CCO were also its general counsel, much of the information about its compliance program could potentially be protected from third-party review, including the Commission's, under the shroud of attorney-client privilege. While there may be circumstances where the attorney-client privilege could be asserted by a SEF, the Commission believes that such circumstances do not include the areas of responsibility assigned to CCOs by the CEA or Commission regulations.

[104] Proposed § 37.1501(a) defines board of directors for purposes of subpart P as follows: "the board of directors or board of governors of a swap execution facility, or equivalent governing body of a swap execution facility or of an entity operating a swap execution facility." The proposed definition reflects the various forms of business associations which a SEF could take, including forms which do not include a corporate board of directors. With respect to boards of directors and ROCs, the Commission notes that in a separately proposed series of regulations governing conflicts of interest within SEFs, DCMs, and DCOs, the Commission proposes a number of governance measures that impact the proposed regulations for CCOs. First, proposed § 40.9(b)(1)(i) requires a SEF's board of directors to be composed of at least 35%, but no less than two, public directors. Second, proposed § 40.9(b)(2) prohibits a SEF from "permit[ing] itself

that ROCs will help to mitigate potential conflicts of interest within a SEF by introducing an independent perspective to board deliberations.[105] The Commission also believes that both CCOs and ROCs will be strengthened in their regulatory work and independence through close cooperation and coordination. Although a CCO is not required to report to his or her ROC, proposed § 37.1501(c)(1) provides that a CCO must meet with the ROC quarterly to discuss matters of mutual concern and share information. These meetings will create an opportunity for a CCO and the ROC to speak freely about potentially sensitive issues, including any reservations by the CCO regarding the SEF's management. They will also facilitate the ROC's oversight responsibilities, and allow the CCO to seek assistance and institutional support from the ROC as necessary.

Finally, proposed § 37.1501(c)(1) also provides that the senior officer of a SEF may assume responsibility for appointing the CCO and approving his or her compensation.

Proposed § 37.1501(c)(2) addresses routine oversight of a SEF's CCO. It allows a SEF with a board of directors to grant oversight authority to either its board or to its senior officer. The proposed regulation is modeled on the terms of Section 5h(f)(15)(B)(i) of the CEA, which requires a CCO to "report directly to the board or to the senior officer of the facility."

Request for Comment:

The Commission requests comment regarding the appropriate reporting relationship for the CCO of a SEF that has both a senior officer and a board of directors.

- In such cases, should a CCO report to the SEF's board rather than to its senior officer?
- What potential conflicts of interest might arise if a CCO reports to the senior officer rather than to the board, and how might those conflicts be mitigated?
- In addition, the Commission requests comment regarding whether "senior officer" of a SEF should be a defined term, and if so, how the term should be defined.

d. Removal of CCO—Proposed § 37.1501(c)(3)

Proposed § 37.1501(c)(3) requires approval of a majority of an SDR's board of directors to remove a CCO. The Commission believes that these removal provisions will help insulate CCOs and their decision-making from day-to-day commercial pressures that they may otherwise experience. If a SEF does not have a board, the proposed regulation provides that the CCO may be removed by its senior officer. Proposed § 37.1501(c)(3) also requires an SDR to notify the Commission in writing within two business days of the removal or voluntary departure of its CCO by providing a statement describing the circumstances surrounding his or her departure.[106] The Commission believes that this provision will help protect CCOs from undue influence or retaliatory termination by the board or the senior officer of the SEF.

Proposed §§ 37.1501(c)(1) and 37.1501(c)(3) seek to provide a SEF's CCO with a measure of independence from management in the performance of his or her duties, and to ensure that such duties are executed in the most effective and impartial manner possible.

Request for Comment:

The Commission requests comment on any additional measures that should be required to adequately protect CCOs from undue influence in the performance of their duties. The Commission is particularly interested in how it might offer such protection to a CCO who reports to his or her senior officer, either at the SEF's choosing or because the SEF does not have a board of directors. In addition, the Commission also requests comment on whether the provision that would require a majority of a board of directors to remove the CCO is sufficiently specific.

e. Duties of the Chief Compliance Officer—Proposed § 37.1501(d)

Proposed § 37.1501(d) details the duties of a CCO, as well as his or her authority within a SEF. The proposed regulation codifies and expands upon the CCO duties already set forth in Section 5h(f)(15)(B) of the CEA. These duties include overseeing and reviewing compliance with the CEA and Commission regulations, as well as resolving, in consultation with the board of directors or the senior officer, any conflicts of interest that may arise. The proposed regulation also lists a number of potential conflicts that may confront a CCO. The list of conflicts of interest indicates the types of conflicts that the Commission believes a SEF's CCOs should be aware of, but it is not exhaustive.

Proposed § 37.1501(d) also requires that the CCO establish and administer a written code of ethics and policies and procedures designed to prevent violations of the CEA and Commission regulations. Section 37.1501(d) also requires that a CCO establish and administer written policies and procedures, including a "compliance manual," designed to prevent violations of the CEA and Commission regulations.[107]

The Commission believes that such written documentation will serve as a useful guide for the SEF's management and staff, as well as for swap participants who will be trading on the SEF. It will also help the Commission to evaluate the SEF's compliance and adherence to its own internal standards. Finally, proposed § 37.1501(d) requires that a CCO establish and follow procedures for the remediation and closing of any noncompliance issues that are identified. To assist the CCO in meeting this responsibility, proposed § 37.1501(b)(1), summarized above, grants a CCO oversight authority over all compliance functions and staff acting in furtherance of those compliance functions. The CCO's authority would also extend to any activities performed by the SEF to verify that other entities are in compliance with applicable laws and regulations, such as the verification of the timeliness of reporting certain swap data, pursuant to proposed § 37.901. The Commission recognizes that the staff that assists a CCO may not be dedicated to the CCO full-time; however, the proposed regulation would ensure that a CCO has authority over any staff and resources while they are acting in furtherance of compliance functions.

Section 37.1501(d), for example, reflects the statutory text of the Dodd-Frank Act by requiring that a CCO review and ensure a SEF's compliance

to be operated by any entity" that does not adhere to the board composition requirements of 40.9(b)(1)(i). Third, proposed § 37.19(b)(3) requires a SEF to have a board-level ROC consisting exclusively of public directors.

[105] *See* proposed § 37.19(b)(1) for a description of a ROC's role in overseeing the performance of a CCO and effectiveness, efficiency, and independence of a SEF's regulatory and self-regulatory programs.

[106] Upon the departure of a CCO, proposed § 37.1501(c)(3) requires a SEF to appoint an interim CCO immediately and a permanent replacement as soon as practicable.

[107] By "compliance manual," the Commission means a detailed internal handbook explaining to SEF staff the resources and procedures that they are to use in monitoring trading, conducting investigations, documenting their work, and making findings and recommendations to supervisory staff regarding trading in any swap or other conduct by SEF members and market participants that is subject to SEF rules. The Commission believes that such written documentation will serve as a useful guide for the SEF's management and staff. It will also help the Commission evaluate the SEF's compliance and adherence to its own internal standards.

with the CEA and Commission regulations. It also reflects a CCO's responsibilities with respect to the regulation of members and market participants utilizing a SEF's trading platform. In this regard, Section 37.1501(d)(8) requires that a CCO supervise a SEF's self-regulatory program with respect to trade practice surveillance; market surveillance; real-time market monitoring; compliance with audit trail requirements; enforcement and disciplinary proceedings; and audits, examinations, and other regulatory responsibilities with respect to members and market participants. Similarly, Section 37.1501(d)(9) requires that a CCO supervise the effectiveness and sufficiency of any regulatory services provided to the SEF by a registered futures association or other registered entity in accordance with § 37.204.[108]

Request for Comment:

The Commission requests comment regarding proposed § 37.1501(d). Comments should address any additional CCO duties which the Commission should include in the proposed regulation. In addition, they should specifically address a CCO's role in managing conflicts of interest within a SEF, the types of conflicts which commenters believe might arise within a SEF, and how and by whom those conflicts should be resolved.

f. Preparation and Submission of Annual Compliance Report—Proposed §§ 37.1501(e) and 37.1501(f)

Section 5h(f)(15)(D) of the CEA requires a CCO to prepare an annual compliance report. As discussed above, the Commission believes that this annual compliance report should give the Commission a complete and accurate picture of a SEF's compliance program. Proposed § 37.1501(e) details the information that must be included in the annual compliance report. The report must include: (i) A description of the SEF's written policies and procedures, code of ethics and conflicts of interest policies; (ii) a detailed review of the SEF compliance with Section 5h of the CEA, including an assessment by the CCO of the effectiveness of the SEF's policies and procedures in ensuring compliance with Section 5h of the CEA and a discussion of areas for improvement; (iii) a description of any material changes to the policies and procedures that were made to these since the last annual compliance report; (iv) a description of the financial, managerial, operational, and staffing resources set aside for the SEF's compliance program, including a description of the SEF's compliance program, describing resources set aside for the SEF's self-regulatory responsibilities. An annual compliance report must also provide: a detailed description and review of the SEF's self-regulatory program, which includes a description of staff associated with self-regulation, a catalogue of investigations and disciplinary actions taken, and a review of the performance of disciplinary committees and panels; (v) a description of any material compliance matters, including instances of noncompliance, that were identified in the year prior to the filing of the report; and (vi) any objections to the annual compliance report by the board or senior officer of the SEF. In addition to the above information, proposed § 37.1501(e) also requires the annual report to include a certification by the CCO that, under penalty of law, the compliance report is accurate and complete.

Proposed § 37.1501(f)(1) sets forth the procedures for the review of the annual compliance report by the board of directors of the SEF or senior officer, prior to submission to the Commission. While the board or senior officer has a chance to review the annual compliance report before submission, the report is not subject to their approval. Proposed § 37.1501(f)(1) explicitly prohibits the board or senior officer from forcing the CCO to make any material changes to the report. The purpose of this review is to permit the members of the board or the senior officer to provide the Commission with any objections they might have to the report. The Commission believes that the prohibition against the board and senior officer making changes to the annual compliance report will allow the CCO to make a complete and accurate assessment of the SEF's compliance program.

Proposed § 37.1501(f)(2) describes the process for submission of the report to the Commission. The proposed regulation requires that the annual compliance report be electronically provided to the Commission not more than 60 days after the end of the calendar year. If a CCO determines that an annual compliance report filed with the Commission has a material error or if material non-compliance is identified after filing, proposed § 37.1501(f)(3) would require a SEF to promptly file an amended report. This amended report must also include the certification by the CCO as to the accuracy and completeness made in the initial submission of the report. If a CCO is unable to file an annual compliance report within 60 days of the end of the calendar year, proposed § 37.1501(f)(4) would permit a CCO to request the Commission to grant an extension of time to file its compliance report based on substantial undue hardship. Extensions for the filing deadline would be granted at the discretion of the Commission. Additionally, to protect the trade secrets of the SEF and the security of the data held by the SEF, the proposed regulation requires that annual compliance reports filed pursuant to § 37.1501 be treated as exempt from mandatory public disclosure for purposes of FOIA and the Sunshine Act and parts 145 and 147 of Commission regulations.

Request for Comment:

The Commission requests comment on its proposed regulations regarding the preparation and submission of a SEF's annual compliance report.

- Should the annual compliance report contain additional content beyond what is proposed in § 37.1501(e)? Are additional provisions necessary to ensure that a SEF's board of directors cannot adversely influence the content of an annual compliance report as drafted by the CCO?
- In the alternative, are additional provisions necessary to ensure that individual directors or other SEF employees have an adequate opportunity to register any concerns or objections they might have to the contents of an annual compliance report?

The Commission also requests comment relating to insulating a SEF's CCO from undue influence or coercion.

- Should the Commission adopt a regulation that prohibits an officer, director or employee of the SEF or related person to coerce, manipulate, mislead, or fraudulently influence the CCO in performing his or her duties?
- Is it necessary to adopt regulations to address potential conflicts between and among a SEF's compliance, commercial, and ownership interests?
- If so, what should such regulations entail, and what specific conflicts of interest should they address?

g. Recordkeeping—Proposed § 37.1501(g)

Proposed § 37.1501(g) details SEFs' recordkeeping requirements for records relating to a CCO's areas of responsibility. This proposed regulation requires a SEF to maintain: (i) A copy of its written policies and procedures,

[108] *See* proposed § 37.204 (governing a SEF's use of third-party regulatory service providers and its duty to supervise such providers and any services received).

including its code of ethics and conflicts of interest policies; (ii) copies of all materials created in furtherance of the chief compliance officer's self-regulatory duties, including records of any investigations or disciplinary actions taken by the SEF; (iii) copies of all materials, including written reports provided to the board of directors in connection with review of the annual report, as well as the board minutes or other similar written records, that record the submission of the annual compliance report to an SEF's board of directors or its senior officer; and (iv) any other records relevant to an SEF's annual report. The records required to be maintained pursuant to this section are designed to provide Commission staff with a basis to determine whether a SEF has complied with the CEA and applicable Commission regulations. The Commission also wants to preserve its ability to reconstruct why certain information was included or excluded in an annual report, in the event that such reconstruction becomes necessary under a future audit or investigation.

The SEF would be required to maintain these records in accordance with § 1.31 of the Commission's regulations. Following § 1.31, all records must be kept for a period of five years.

Request for Comment:

The Commission requests comment regarding whether the requirements of proposed § 37.1501(g) are sufficient to create a complete and easily auditable record of a board of directors' or senior officer's review of an annual compliance report to ensure that the report, as drafted by the CCO, was not altered.

III. Effective Date and Transition Period

The statutory deadline for final regulations is July 15, 2011. Final regulations may become effective sixty (60) days after their publication in the **Federal Register**, but no earlier than July 15, 2011. The Commission is proposing that the effective date for the proposed regulations be 90 days after publication of final regulations in the **Federal Register**. The Commission believes that the effective date would be appropriate to allow potential SEFs and market participants time to adapt to the new regulatory regime for the trading of swaps in an efficient and orderly manner. In addition, the Commission believes that this would give any entities then operating a marketplace for the execution or trading of swaps adequate time to submit a SEF application and meet the conditions to receive relief under the grandfather provisions.

Request for Comment:

The Commission requests comment on whether the proposed effective date is appropriate and, if not, the Commission further requests comment on possible alternative effective dates and the basis for any such alternative dates.

IV. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA") [109] requires Federal agencies, in promulgating regulations, to consider the impact of those regulations on small businesses. The regulations adopted herein will affect SEFs. The Commission has previously established certain definitions of "small entities" to be used by the Commission in evaluating the impact of its regulations on small entities in accordance with the RFA.[110] In its previous determinations, the Commission has concluded that DCMs, derivatives transaction execution facilities ("DTEFs"), ECMs, EBOTs and DCOs are not small entities for the purpose of the RFA.[111]

While SEFs are new entities to be regulated by the Commission pursuant to the Dodd-Frank Act,[112] in a recent rulemaking proposal,[113] the Commission proposed that SEFs should not be considered as small entities for the purpose of the RFA. The Dodd-Frank Act defines a SEF to mean "a trading system or platform in which multiple participants have the ability to execute or trade swaps by accepting bids and offers made by multiple participants in the facility or system, through any means of interstate commerce, including any trading facility, that—(A) facilitates the execution of swaps between persons; and (B) is not a designated contract market." [114] In its recent rulemaking, the Commission proposed that SEFs not be considered to be "small entities" for essentially the same reasons that DCMs and DCOs have previously been determined not to be small entities. These reasons include the fact that the Commission designates a DCM or registers a DCO only when it meets specific criteria including expenditure of sufficient resources to establish and maintain adequate self-regulatory programs. Likewise, the Commission will register an entity as a SEF only after it has met specific criteria including the expenditure of sufficient resources to establish and maintain an adequate self-regulatory program. In addition, once registered, a SEF will be required to comply with the additional requirements set forth in the final form of this proposed Part 37 rulemaking. In addition, the Commission proposes that SEFs should not be considered small entities based on, among other things, the central role SEFs will play in the national regulatory scheme overseeing the trading of swaps. Not only will SEFs play a vital role in the national economy, but they will be subject to Commission oversight with statutory duties to enforce the regulations adopted by their own governing bodies.

Accordingly, the Commission does not expect the regulations, as proposed herein, to have a significant economic impact on a substantial number of small entities. Therefore, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the proposed regulations will not have a significant economic impact on a substantial number of small entities. The Commission invites the public to comment on whether SEFs covered by these rules should be considered small entities for purposes of the RFA.

B. Paperwork Reduction Act

The Paperwork Reduction Act ("PRA") [115] imposes certain requirements on Federal agencies in connection with their conducting or sponsoring any collection of information as defined by the PRA. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. This proposed rulemaking will result in new collection of information requirements within the meaning of the PRA. The Commission therefore is submitting this proposal to the Office of Management and Budget (OMB) for review in accordance with 44 U.S.C. 3507(d) and 5 CFR 1320.11. The title for this collection of information is "Part 37—Swap Execution Facilities" (OMB control number 3038–NEW). If adopted, responses to this collection of information would be mandatory. The Commission will protect proprietary

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[109] 5 U.S.C. 601 *et seq.*

[110] 47 FR 18618–21 (Apr. 30, 1982).

[111] 47 FR 18618, 18619 (April 30, 1982) discussing contract markets; 66 FR 42256, 42268 (August 10, 2001) discussing derivatives transaction execution facilities, exempt commercial markets and exempt boards of trade; and 66 FR 45604, 45609 (August 29, 2001) discussing DCOs.

[112] Dodd Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (2010).

[113] 75 FR 63745–46 (October 18, 2010).

[114] *See* CEA Section 1a(50). The Commission anticipates proposing regulations that would further specify those entities that must register as a SEF. The Commission does not believe that such proposals would alter its determination that a SEF is not a "small entity" for purposes of the RFA.

[115] 44 U.S.C. 3501 et seq.

information according to the Freedom of Information Act and 17 CFR part 145, "Commission Records and Information." In addition, section 8(a)(1) of the CEA strictly prohibits the Commission, unless specifically authorized by the CEA, from making public "data and information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers."[116] The Commission is also required to protect certain information contained in a government system of records according to the Privacy Act of 1974.[117]

1. Collection of Information—Regulations Relating to Part 37, Swap Execution Facilities

The proposed regulations require each respondent to file information with the Commission. For instance, SEFs must file applications with the Commission for registration pursuant to § 37.3. SEFs must either request approval with, or certify to, the Commission rules and products, pursuant to § 37.4. SEFs must disclose information related to prices, trading volume, and other trading data on swaps pursuant to Core Principle 9 (Timely Publication of Trading Information).

Commission staff has previously estimated hourly burdens for DCMs and DTEFs pursuant to the Commodity Futures Modernization Act of 2000 ("CFMA").[118] More recently, Commission staff estimated hourly burdens for ECMs with significant price discovery contracts ("SPDCs"). While the Commission has no way of knowing the exact hourly burden upon a registered entity prior to implementation of the regulations governing that registered entity, staff believes the estimated burden for a SEF would be within the range of previously estimated hours of burden for the above registered entities. Those hourly burdens are noted below:

Initial estimate of DCM's annual burden[119]: 300 hours per DCM.

Estimate of DCM's annual burden as of 2006[120]: 370 hours per DCM.

Current estimate of DCM's annual burden[121]: 440 hours per DCM.

Initial estimate of DTEF's annual burden[122]: 200 hours per DTEF.

Initial estimate of ECM's with SPDCs annual burden[123]: 233 hours per ECM.

Based on the proposed regulations, Commission staff believes that a SEF will have *more* reporting responsibilities than an ECM with a SPDC and a DTEF, but *fewer* reporting hours than a DCM (as most recently calculated).[124] Based on its experience with administering registered entities' submission requirements since implementation of the CFMA, Commission staff estimates an annual reporting burden for SEFs to be an average of the above noted estimates for DCMs, DTEFs and ECMs with SPDCs.

Staff estimates that each respondent would, on average, have an annual burden of 308 hours of reporting time. Staff estimates that 30–40 SEFs will register with the Commission as a result of the Dodd-Frank Act.[125] Accordingly, the burden in terms of hours would in the aggregate be 308 hours annually per respondent and 10,780 hours annually for all respondents.

Commission staff estimates that respondents could expend up to $16,016 annually based on an hourly rate of $52 to comply with the proposed regulations. This would result in an aggregated cost of $560,560 per annum (35 respondents × $16,016).

Estimated Number of respondents: 35.

Annual Responses by each respondent: 1.

Total annual responses: 35.

Quarterly responses by each respondent: 4.

Total quarterly responses: 140.

Estimated average hours per response: 308.

Aggregate annual reporting burden: 10,780.

2. Information Collection Comments

Copies of the supporting statements for the collections of information from the Commission to OMB are available by visiting RegInfo.gov. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission will consider public comments on the proposed information requirements in order to:

(1) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;

(2) Evaluate the accuracy of the estimated burden of the proposed information collection requirements, including the degree to which the methodology and the assumptions that the Commission employed were valid;

(3) Enhance the quality, utility, and clarity of the information proposed to be collected; and

(4) Minimize the burden of the proposed information collection requirements on DCOs, DCMs, and SEFs, including through the use of appropriate automated, electronic, mechanical, or other technological information collection techniques, *e.g.,* permitting electronic submission of responses.

Organizations and individuals desiring to submit comments on the proposed information collection requirements should contact the Office of Information and Regulatory Affairs, Office of Management and Budget by fax at (202) 395–6566 or by e-mail at *OIRAsubmission@omb.eop.gov*. Please provide the Commission with a copy of submitted comments so that they may be summarized and address in the final rulemaking. Refer to the **ADDRESSES** section of this notice of proposed rulemaking for comment submission instructions to the Commission.

OMB is required to make a decision concerning the proposed information collection requirements between 30 and 60 days after publication of this Release in the **Federal Register**. Therefore, a comment to OMB is best assured of receiving full consideration if OMB receives it within 30 days of publication of this Release. Nothing in the foregoing affects the deadline enumerated above for public comment to the Commission on the proposed regulations.

C. Cost-Benefit Analysis

Section 15(a) of the CEA[126] requires that the Commission consider the costs and benefits of its actions before issuing a regulation under the CEA. By its terms, Section 15(a) does not require the Commission to quantify the costs and benefits of a new rule or determine whether the benefits of the rulemaking outweigh its costs; rather, Section 15(a) requires the Commission to "consider" the costs and benefits of its actions.

Section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. Accordingly, the Commission could, in its discretion, give greater weight to any one of the five considerations and could, in its discretion, determine that,

[116] 7 U.S.C. 12(a)(1).

[117] 5 U.S.C. 552a.

[118] Appendix E of Public Law 106–554, 114 Stat. 2763 (2000).

[119] 66 FR 38992 (June 22, 2000).

[120] 71 FR 38748 (July 7, 2006).

[121] *See, supra* note 10, DCM NPRM.

[122] 65 FR 38993 (June 22, 2000).

[123] 73 FR 75901 (December 12, 2008).

[124] ECMs with SPDCs are subject to 9 core principles, DTEFs are subject to 9 core principles, DCMs are currently subject to 18 core principles, (but will be subject to 23 core principles upon finalization of the Part 38 regulations implementing the Dodd-Frank Act). SEFs will be subject to 15 core principles upon finalization of the regulations to implement the Dodd-Frank Act.

[125] For hourly reporting requirements, an average of 35 SEFs was used for calculation purposes.

[126] 7 U.S.C. 19(a).

notwithstanding its costs, a particular rule was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA.

Summary of Proposed Requirements

The proposed rulemaking would provide, pursuant to the Dodd-Frank Act, for the trading or processing of swaps on a registered SEF subject to 15 core principles. This rulemaking will implement, in Part 37 of the Commission's regulations, these provisions of the CEA. The proposal includes regulations as well as guidance and acceptable practices to implement these core principles. In general, the proposed regulations implementing core principles for SEFs are consistent with the existing or proposed regulations for similar or identical core principles applicable to DCMs.

Costs

As highlighted by recent events in the global credit markets, transacting of swaps in unregulated, over-the-counter markets does not contribute to the goal of stability in the broader financial markets. The public would continue to be at risk to such financial instability if certain derivatives were allowed to trade over the counter rather than on regulated exchanges. SEFs that determine to register with the Commission in order to provide for the transacting of swaps will be subject to core principles for transacting of swaps. If swaps were allowed to continue to be transacted bilaterally, rather than on the regulated market of a SEF, price discovery and transparency in the swaps markets would continue to be inhibited. These procedures are mandatory pursuant to the Dodd-Frank Act and any additional costs associated with these procedures are required by the implementation of the Dodd-Frank Act.

Benefits

The Commission believes that the benefits of the rulemaking are significant. The proposed regulations provide for the transacting of swaps on SEFs. SEFs will compete with DCMs that make certain swaps available for trading, while certain swaps will continue to transact bilaterally. This competition will benefit the marketplace. Providing market participants with the ability to trade certain swaps openly and competitively on a SEF complying with all of the SEF core principles as well as on DCMs complying with DCM core principles will provide market participants with additional choices and will enhance price transparency resulting in protection of market participants and the public. The proposed regulations will necessitate that SEFs that determine to make certain swaps available for trading will have to coordinate with DCOs in order to effect clearing and thus be subject to the DCO's risk management and margining procedures.

Request for Comment:

The Commission invites public comment on its cost-benefit considerations. Commenters are also invited to submit any data or other information that they may have quantifying or qualifying the costs and benefits of the proposal with their comment letters.

V. Text of the Proposed Regulations, Guidance and Acceptable Practices

List of Subjects in 17 CFR Part 37

Swaps, Swap execution facilities, Registration application, Registered entities, Reporting and recordkeeping requirements.

In light of the foregoing, and pursuant to authority in the CEA, and, in particular, Sections 3, 5, 5c(c), 8a(5) and 21 of the CEA, the Commission hereby proposes to revise part 37 of Title 17 of the Code of Federal Regulations to read as follows:

PART 37—SWAP EXECUTION FACILITIES

Subpart A—General Provisions

Sec.

Subpart B—Compliance with Core Principles

Sec.

Subpart C—Compliance with Rules

Sec.

Subpart D—Swaps Not Readily Susceptible to Manipulation

Sec.

Subpart E—Monitoring of Trading and Trade Processing

Sec.

Subpart F—Ability to Obtain Information

Sec.

Subpart G—Position Limits or Accountability

Sec.

Subpart H—Financial Integrity of Transactions

Sec.

Subpart I—Emergency Authority

Sec.

Subpart J—Timely Publication of Trading Information

Sec.

Subpart K—Recordkeeping and Reporting

Sec.

Authority: 7 U.S.C. 1a, 2, 5, 6, 6c, 7, 7a–2, 7b–3 and 12a, as amended by Titles VII and VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 124 Stat. 1376 (2010).

Subpart A—General Provisions

§ 37.1 Scope.

The provisions of this part 37 shall apply to every swap execution facility that is registered, has been registered or is applying to become registered as a swap execution facility under Section 5h of the Act. Provided, however, nothing in this provision affects the eligibility of swap execution facilities to operate under the provisions of Parts 38 or 49 of this Chapter.

§ 37.2 Applicable provisions.

A swap execution facility, the swap execution facility's operator and transactions traded on or through a swap execution facility under Section 5h of the Act shall comply with the requirements of this part 37, and §§ 1.3, 1.12(e), 1.31, 1.37(c)–(d), 1.52, 1.59(d), 1.60, 1.63(c), 1.67, 33.10, part 9, parts 15 through 21, part 40, part 41, part 43, part 45, part 46, part 49, part 151, and part 190 of this chapter, including any related definitions and cross-referenced sections.

§ 37.3 Requirements for registration.

(a) *Application procedures.* (1) An applicant seeking registration as a swap execution facility must file electronically an application for registration with the Secretary of the Commission, in the form and manner as provided by the Commission. The Commission shall approve or deny the application or, if deemed appropriate, register the applicant as a swap execution facility subject to conditions.

(2) The application must include information sufficient to demonstrate compliance with the core principles specified in Section 5h of the Act. The Application Form SEF consists of instructions, general questions and a list of Exhibits (documents, information and evidence) the Commission requires in order to be able to determine whether an applicant is able to comply with the core principles. An application will not be considered to be materially complete unless the applicant has submitted, at a minimum, the Exhibits as required in Application Form SEF. If the application is not materially complete, the Commission shall notify the applicant that the application will not be deemed to have been submitted for purposes of the Commission's review.

(3) An applicant seeking registration must request from the Commission a unique, extensible, alphanumeric code for the purpose of identifying the swap execution facility pursuant to Part 45 of this chapter.

(4) An applicant seeking registration must identify with particularity any information in the application that will be subject to a request for confidential treatment pursuant to § 145.9 of this Chapter.

(5) Section 40.8 of this Chapter sets forth those sections of the application that will be made publicly available, notwithstanding a request for confidential treatment pursuant to § 145.9 of this Chapter.

(6) If any information contained in the application or any Exhibit is or becomes inaccurate for any reason, an amendment to the application or a submission filed under Part 40 of this Chapter must be filed promptly correcting such information.

(7) The Commission hereby delegates, until it orders otherwise, to the Director of the Division of Market Oversight or such other employee or employees as the Director may designate from time to time, upon consultation with the General Counsel or the General Counsel's delegate, authority to notify the applicant seeking registration that the application is materially incomplete and the review is stayed. The Director may submit to the Commission for its consideration any matter that has been delegated in this paragraph. Nothing in this paragraph prohibits the Commission, at its election, from exercising the authority delegated in this paragraph.

(b) *Temporary Grandfather Relief from Registration.* Concurrent with the completion of the application procedures under paragraph (a) of this section, an applicant may submit a notice requesting that the Commission grant the applicant temporary grandfather relief from the registration requirement, allowing it to continue operating during the pendency of the application process.

(1) The Commission may grant such request for temporary grandfather relief from the registration requirement if the applicant has:

(i) Satisfied all the requirements under paragraph (a) of this section,

(ii) Provided transaction data that substantiates that the execution or trading of swaps has occurred and continues to occur on the applicant's trading system or platform at the time the applicant submits the request, and

(iii) Provided a certification that the applicant believes that when it operates under temporary grandfather relief it will meet the requirements of this Part 37.

(2) The temporary grandfather relief for a swap execution facility shall expire on the earlier of:

(i) The date that the Commission grants or denies registration of the swap execution facility; or

(ii) The date that the Commission rescinds the temporary grandfather relief provided to the swap execution facility.

(3) The grant of temporary grandfather relief from the registration requirement by the Commission does not affect the right of the Commission to grant or deny permanent registration as provided under paragraph (a)(1) of this section. This paragraph shall terminate 365 days from the effectiveness of this regulation.

(c) *Reinstatement of dormant registration.* Before making any swaps available for trading, a dormant swap execution facility as defined in § 40.1 of this Chapter must reinstate its registration under the procedures of paragraph (a) of this section; provided, however, that an application for reinstatement may rely upon previously submitted materials that still pertain to,

and accurately describe, current conditions.

(d) *Request for transfer of registration.* (1) Request for transfer of registration. A swap execution facility that wants to request the transfer of its registration from its current legal entity to a new legal entity, as a result of a corporate reorganization or otherwise, must file a request with the Commission for approval to transfer the registration. Such request must be filed electronically with the Secretary of the Commission at its Washington, DC headquarters at *submissions@cftc.gov* and the Division of Market Oversight at *DMOSubmissions@cftc.gov.*

(2) *Timing of submission.* The request must be filed no later than three months prior to the anticipated corporate change; *provided that* the swap execution facility may file a request with the Commission later than three months prior to the anticipated change if the swap execution facility does not know and reasonably could not have known of the anticipated change three months prior to the anticipated change. In such event, the swap execution facility shall be required to immediately file the request with the Commission as soon as it knows of such change with an explanation as to the timing of the request.

(3) *Required information.* The request shall include the following:

(i) The underlying agreement that governs the corporate change;

(ii) A narrative description of the corporate change, including the reason for the change and its impact on the swap execution facility, including its governance, and operations, and its impact on the rights and obligations of market participants;

(iii) A discussion of the transferee's ability to comply with the Act, including the core principles applicable to swap execution facilities, and the Commission's regulations thereunder;

(iv) The governing documents of the transferee, including but not limited to articles of incorporation and bylaws;

(v) The transferee's rules marked to show changes from the current rules of the swap execution facility;

(vi) A representation by the transferee that it:

(A) Will be the surviving corporation and successor-in-interest to the transferor swap execution facility and will retain and assume, without limitation, all the assets and liabilities of the transferor;

(B) Will assume responsibility for complying with all applicable provisions of the Act and the Commission's regulations promulgated thereunder, including Part 37 and Appendices thereto;

(C) Will assume, maintain and enforce all rules implementing and complying with these core principles, including the adoption of the transferor's rulebook, as amended in the request, and that any such amendments will be submitted to the Commission pursuant to Section 5c(c) of the Act and Part 40 of the Commission's regulations; and

(D) Will comply with all self-regulatory responsibilities except if otherwise indicated in the request, and will maintain and enforce all self-regulatory programs.

(vii) A representation by the transferee that upon the transfer:

(A) It will assume responsibility for and maintain compliance with product core principles for all swaps previously made available for trading through the transferor, whether by certification or approval; and

(B) That none of the proposed rule changes will affect the rights and obligations of any participant.

(viii) A representation by the transferee that market participants will be notified of all changes to the transferor's rulebook prior to the transfer and will be further notified of the concurrent transfer of the registration to the transferee upon Commission approval and issuance of an order permitting this transfer.

(4) Commission determination. The Commission will review a request as soon as practicable and such request will be approved or denied pursuant to a Commission order and based on the Commission's determination as to the transferee's ability to continue to operate the swap execution facility in compliance with the Act and the Commission's regulations thereunder.

(e) *Request for withdrawal of application for registration.* An applicant for registration may withdraw its application submitted pursuant to paragraph (a) of this section by filing such a request with the Commission at its Washington, DC headquarters. Withdrawal of an application for registration shall not affect any action taken or to be taken by the Commission based upon actions, activities or events occurring during the time that the application for registration was pending with the Commission.

(f) *Request for vacation of registration.* A swap execution facility may vacate its registration under Section 7 of the Act by filing electronically such a request with the Commission at its Washington, DC headquarters. Vacation of registration shall not affect any action taken or to be taken by the Commission based upon actions, activities or events occurring during the time that the swap execution facility was registered by the Commission.

§ 37.4 Procedures for Listing Products and Implementing Rules.

(a) *Request for Commission approval of rules and products.* (1) An applicant for designation, or a swap execution facility, may request that the Commission approve under Section 5c(c) of the Act, any or all of its rules and contract terms and conditions, and subsequent amendments thereto, prior to their implementation or, notwithstanding the provisions of Section 5c(c)(2) of the Act, at anytime thereafter, under the procedures of §§ 40.3 or 40.5 of this chapter, as applicable. A swap execution facility should label a swap in its rules as "Listed for trading pursuant to Commission approval," if the swap and its terms or conditions have been submitted to the Commission for approval, and it may label as "Approved by the Commission" only those rules that have been so approved.

(2) Notwithstanding the timeline under §§ 40.3(b) and 40.5(b) of this Chapter, the operating rules and terms and conditions of swaps submitted for Commission approval that have been submitted at the same time as an application for swap execution facility registration or an application under § 37.3(c) to reinstate the registration of a dormant swap execution facility as defined in § 40.1 of this Chapter, or while one of the foregoing is pending, will be deemed approved by the Commission no earlier than when the swap execution facility is deemed to be registered or reinstated.

(b) *Self-certification of rules and products.* Rules of a swap execution facility and subsequent amendments thereto, including both the operational rules and the terms or conditions of swaps listed for trading on the facility, not voluntarily submitted for prior Commission approval pursuant to paragraph (a) of this regulation, must be submitted to the Commission with a certification that the rule or rule amendment of the swap complies with the Act or rules thereunder pursuant to the procedures of § 40.2 or § 40.6 of this Chapter, as applicable.

(c) *Section 15 consideration.* An applicant for registration, or a registered swap execution facility, may request that the Commission consider under the provisions of Section 15(b) of the Act any of the swap execution facility's rules or policies, including both the operational rules and the terms or conditions of swaps listed for trading.

§ 37.5 Information Relating to Swap Execution Facility Compliance.

(a) *Requests for information.* Upon request by the Commission, a swap execution facility must file with the Commission such information related to its business as a swap execution facility, including information relating to data entry and trade details, in the form and manner and within the time as specified by the Commission in its request.

(b) *Demonstration of compliance.* Upon request by the Commission, a swap execution facility must file with the Commission a written demonstration, containing such supporting data, information and documents, in the form and manner and within such time as the Commission may specify, that the swap execution facility is in compliance with one or more core principles as specified in the request, or that is requested by the Commission to satisfy its obligations under the Act.

(c) *Equity interest transfers.* (1) Equity transfer notification. Upon entering into any agreement(s) that could result in an equity interest transfer of ten percent or more in the swap execution facility, the swap execution facility must file a notification of the equity interest transfer with the Secretary of the Commission at its Washington, DC headquarters at *submissions@cftc.gov* and the Division of Market Oversight at *DMOSubmissions@cftc.gov,* no later than the business day, as defined in § 40.1 of this Chapter, following the date on which the swap execution facility enters into a firm obligation to transfer the equity interest.

(2) Required information. The notification must include and be accompanied by: Any relevant agreement(s), including any preliminary agreements; any associated changes to relevant corporate documents; a chart outlining any new ownership or corporate or organizational structure; a brief description of the purpose and any impact of the equity interest transfer; and a representation from the swap execution facility that it meets all of the requirements of Section 5h of the Act and Commission regulations adopted thereunder. The swap execution facility must keep the Commission apprised of the projected date that the transaction resulting in the equity interest transfer will be consummated, and must provide to the Commission any new agreements or modifications to the original agreement(s) filed pursuant to this section. The swap execution facility must notify the Commission of the consummation of the transaction on the day on which it occurs.

(3) Certification. (i) Upon a transfer of an equity interest of ten percent or more in a swap execution facility, the swap execution facility must file with the Secretary of the Commission at its Washington, DC headquarters, at *submissions@cftc.gov,* and the Division of Market Oversight, at *DMOSubmissions@cftc.gov,* a certification that the swap execution facility meets all of the requirements of Section 5h of the Act and Commission regulations adopted thereunder, no later than two business days, as defined in § 40.1 of this Chapter, following the date on which the equity interest of ten percent or more was acquired. Such certification must state whether changes to any aspects of the swap execution facility's operations were made as a result of such change in ownership, and include a description of any such change(s).

(ii) The certification required under paragraph (c)(3) of this section may rely on and be supported by reference to an application for registration or prior filings made pursuant to a product or rule submission requirement, along with any necessary new filings, including new filings that provide any and all material updates of prior submissions.

(d) *Delegation of authority.* The Commission hereby delegates, until it orders otherwise, the authority set forth in paragraph (b) of this regulation to the Director of the Division of Market Oversight or such other employee or employees as the Director may designate from time to time. The Director may submit to the Commission for its consideration any matter that has been delegated in this paragraph. Nothing in this paragraph prohibits the Commission, at its election, from exercising the authority delegated in this paragraph.

§ 37.6 Enforceability.

(a) A transaction entered into on or pursuant to the rules of a registered swap execution facility shall not be void, voidable, subject to rescission or otherwise invalidated or rendered unenforceable as a result of:

(1) A violation by the registered swap execution facility of the provisions of Section 5h of the Act or this part 37; or

(2) Any Commission proceeding to alter or supplement a rule, term or condition under Section 8a(7) of the Act, to declare an emergency under Section 8a(9) of the Act, or any other proceeding the effect of which is to alter, supplement, or require a registered swap execution facility to adopt a specific term or condition, trading rule or procedure or to take or refrain from taking a specific action.

(b) A transaction entered into on or pursuant to the rules of a registered swap execution facility shall include written documentation that memorializes all of the terms of the transaction and legally supersedes any previous agreement. The confirmation of all terms of the transaction shall take place at the same time as execution.

§ 37.7 Prohibited use of data collected for regulatory purposes.

A swap execution facility may not use for business or marketing purposes any proprietary data or personal information it collects or receives, from or on behalf of any person, for the purpose of fulfilling its regulatory obligations; *provided, however,* that a swap execution facility, where necessary, may share such information with one or more swap execution facilities, or designated contract markets registered with the Commission, for regulatory purposes.

§ 37.8 Boards of trade operating both a designated contract market and a swap execution facility.

(a) A board of trade that operates a designated contract market and intends to also operate a swap execution facility must separately register the swap execution facility, pursuant to the swap execution facility registration requirements set forth in this Part 37, and on an ongoing basis, comply with the core principles under Section 5h of the Act, and the regulations under this part 37.

(b) A board of trade that operates both a designated contract market and a swap execution facility, and that uses the same electronic trade execution system for executing and trading swaps that it uses for executing and trading swaps on the designated contract market must clearly identify to market participants for each swap whether the execution or trading of such swaps is taking place on the designated contract market or on the swap execution facility.

§ 37.9 Permitted execution methods.

(a) *Definitions.* (1) As used in this part 37:

(i) *Order Book* means:

(A) An electronic trading facility, as that term is defined in section 1a(16) of the Act;

(B) A trading facility, as that term is defined in section 1a(51) of the Act;

(C) A trading system or platform in which all market participants in the trading system or platform can enter multiple bids and offers, observe bids and offers entered by other market participants, and choose to transact on such bids and offers; or

(D) Any such other trading system or platform as may be determined by the Commission.

(ii) *Request for Quote System* means:

(A) A trading system or platform in which a market participant must transmit a request for a quote to buy or sell a specific instrument to no less than five market participants in the trading system or platform, to which all such market participants may respond. Any bids or offers resting on the trading system or platform pertaining to the same instrument must be taken into account and communicated to the requester along with the responsive quotes; or

(B) A trading system or platform in which multiple market participants can both:

(*1*) View real-time electronic streaming quotes, both firm and indicative, from multiple potential counterparties on a centralized electronic screen; and

(*2*) Have the option to complete a transaction by:

(*i*) Accepting a firm streaming quote, or

(*ii*) Transmitting a request for quote to no less than five market participants, based upon an indicative streaming quote, taking into account any resting bids or offers that have been communicated to the requester along with any responsive quotes; or

(C) Any such other trading system or platform as may be determined by the Commission.

(iii) *Voice-Based System* means a trading system or platform in which a market participant executes or trades a Permitted Transaction using a telephonic line or other voice-based service.

(iv) *Required Transactions* means transactions that are subject to the execution requirements under this Act and are made available for trading pursuant to § 37.10, and are not block trades.

(v) *Permitted Transactions* means transactions that meet any of these requirements:

(A) Are block trades;

(B) Are not swaps subject to the Act's clearing and execution requirements, or

(C) Are illiquid or bespoke swaps.

(b) *Required Transactions.* (1) Required Transactions may be executed on an Order Book or a Request for Quote System.

(2) An applicant seeking registration as a swap execution facility must, at a minimum, offer trading services to facilitate Required Transactions by providing market participants with the ability to post both firm and indicative quotes on a centralized electronic screen accessible to all market participants who have access to the swap execution facility.

(3) Swap execution facilities must require that traders who have the ability to execute against a customer's order or to execute two customers against each other be subject to a 15 second timing delay between the entry of those two orders, such that one side of the potential transaction is disclosed and made available to other market participants before the second side of the potential transaction (whether for the trader's own account or for a second customer), is submitted for execution.

(4) The Commission may, in its discretion, determine to require the swap execution facility to provide its participants a different trading method for a particular swap.

(c) *Permitted Transactions.* (1) Permitted Transactions may be executed by an Order Book, Request for Quote System, a Voice-Based System, or any such other system for trading as may be permitted by the Commission.

(2) A registered swap execution facility may submit a request to the Commission to offer trading services to facilitate Permitted Transactions. When submitting such request, the swap execution facility must certify its compliance with § 37.11.

§ 37.10 Swaps made available for trading.

(a) A swap execution facility must conduct an annual review (or at the Commission's request) of whether the swap execution facility has made a swap available for trading.

(b) When conducting reviews and assessments regarding whether the swap execution facility has made a swap available for trading, a swap execution facility may consider:

(1) The frequency of transactions in this or similar swaps;

(2) The open interest in this or similar swaps; and

(3) Any other factor requested by the Commission.

(c)(1) If at least one swap execution facility has made the same or an economically equivalent swap available for trading, all swap execution facilities are required to treat the swap as made available for trading.

(2) After conducting its review and assessment of whether a swap is made available for trading, the swap execution facility must provide electronically to the Commission a report of its assessment not more than 30 days after completion of the assessment.

§ 37.11 Identification of non-cleared swaps or swaps not made available to trade.

(a) A swap execution facility may allow:

(1) The execution and trading of swaps that have not been determined to be subject to the clearing mandate under Section 2(h) of the Act;

(2) Transactions subject to an exception from the clearing mandate provided under Section 2(h)(7) of the Act; or

(3) The execution and trading of swaps that have not been made available for trading pursuant to § 37.10.

(b) A swap execution facility that chooses to offer to facilitate bilateral trading for swaps detailed in paragraph (a) of this section must clearly identify to market participants that the particular swap is to be executed bilaterally between the parties pursuant to one of the applicable exemption from execution and clearing.

Subpart B—Compliance With Core Principles

§ 37.100 Core Principle 1—Compliance with Core Principles.

(a) *In general.* To be registered, and maintain registration, as a swap execution facility, the swap execution facility shall comply with—

(1) All core principles described in Section 5h of the Act; and

(2) Any requirement that the Commission may impose by rule or regulation pursuant to Section 8a(5) of the Act.

(b) *Reasonable Discretion of a Swap Execution Facility.* Unless otherwise determined by the Commission by rule or regulation, a swap execution facility described in paragraph (a) of this section shall have reasonable discretion in establishing the manner in which the swap execution facility complies with the core principles described in Section 5h of the Act.

Subpart C—Compliance With Rules

§ 37.200 Core Principle 2—Compliance with rules.

A swap execution facility shall:

(a) Establish and enforce compliance with any rule of the swap execution facility, including the terms and conditions of the swaps traded or processed on or through the swap execution facility and any limitation on access to the swap execution facility;

(b) Establish and enforce trading, trade processing, and participation rules that will deter abuses and have the capacity to detect, investigate, and enforce those rules, including means to provide market participants with impartial access to the market and to capture information that may be used in establishing whether rule violations have occurred;

(c) Establish rules governing the operation of the facility, including rules specifying trading procedures to be used in entering and executing orders traded or posted on the facility, including block trades; and

(d) Provide by its rules that, when a swap dealer or major swap participant enters into or facilitates a swap that is subject to the mandatory clearing requirement of Section 2(h), the swap dealer or major swap participant shall be responsible for compliance with the mandatory trading requirement under Section 2(h)(8) of the Act.

§ 37.201 Operation of swap execution facility and compliance with rules.

(a) A swap execution facility must establish rules governing the operation of the swap execution facility, including, but not limited to, rules specifying trading procedures to be followed by members and market participants when entering and executing orders traded or posted on the swap execution facility, including block trades, as defined in part 45 of this chapter, if offered.

(b) A swap execution facility must establish and impartially enforce compliance with the rules of the swap execution facility, including, but not limited to—

(1) The terms and conditions of any swaps traded or processed on or through the swap execution facility;

(2) Access to the swap execution facility;

(3) Trade practice rules;

(4) Audit trail requirements;

(5) Disciplinary rules; and

(6) Mandatory clearing requirements.

§ 37.202 Access requirements.

(a) *Impartial access by members and market participants.* A swap execution facility shall provide any eligible contract participant and any independent software vendor with impartial access to its market(s) and market services (including any indicative quote screens or any similar pricing data displays), providing—

(1) Criteria that are impartial, transparent, and applied in a fair and nondiscriminatory manner;

(2) A process by which participants provide the swap execution facility with written or electronic confirmation of their status as eligible contract participants, as defined by the Act and Commission regulations, prior to being granted access to the swap execution facility; and

(3) Comparable fees for participants receiving comparable access to, or services from, a swap execution facility.

(b) *Jurisdiction.* Prior to granting any eligible contract participant access to its facilities, a swap execution facility must require that the eligible contract participant consents to its jurisdiction.

(c) *Limitations on access.* A swap execution facility must establish and impartially enforce rules governing any decision to allow, deny, suspend, or permanently bar participants' access to the swap execution facility, including such decisions when made as part of a disciplinary or emergency action taken by the swap execution facility.

§ 37.203 Rule enforcement program.

A swap execution facility must establish and enforce trading, trade processing, and participation rules that will deter abuses and it must have the capacity to detect, investigate and enforce those rules.

(a) *Abusive Trading Practices Prohibited.* A swap execution facility must prohibit abusive trading practices on its markets by members and market participants. Specific trading practices that must be prohibited by all swap execution facilities include front-running, wash trading, pre-arranged trading, fraudulent trading, money passes and any other trading practices that a swap execution facility deems to be abusive. In addition, a swap execution facility also must prohibit any other manipulative or disruptive trading practices prohibited by the Act or by the Commission pursuant to Commission regulation. Swap execution facilities that permit intermediation must prohibit customer-related abuses including, but not limited to, trading ahead of customer orders, trading against customer orders, accommodation trading, and improper cross trading.

(b) *Capacity to Detect and Investigate Rule Violations.* A swap execution facility must have arrangements and resources for effective enforcement of its rules. Such arrangements must include the authority to collect information and documents on both a routine and non-routine basis, including the authority to examine books and records kept by the swap execution facility's members and by market participants. A swap execution facility's arrangements and resources must also facilitate the direct supervision of the market and the analysis of data collected to determine whether a rule violation has occurred.

(c) *Compliance Staff and Resources.* (1) *Sufficient compliance staff.* A swap execution facility must establish and maintain sufficient compliance department resources and staff to ensure that it can conduct effective audit trail reviews, trade practice surveillance, market surveillance and real-time market monitoring. The swap execution facility's compliance staff must also be sufficient to address unusual market or trading events as they arise, and to conduct and complete investigations in a timely manner, as set forth in § 37.203(f).

(2) *Ongoing monitoring of compliance staff resources.* A swap execution facility must monitor the size and workload of its compliance staff on a continuous basis and, on at least an annual basis, formally evaluate the need to increase its compliance resources and staff. In determining the appropriate level of compliance resources and staff, the swap execution facility should consider trading volume increases, the number of new products or swaps listed for trading, any new responsibilities assigned to compliance staff, the results of any internal review demonstrating that work is not completed in an effective or timely manner, the recommendation of any Commission rule enforcement review or evaluation of the swap execution facility and any other factors suggesting the need for increased resources and staff.

(d) *Automated Trade Surveillance System.* A swap execution facility must maintain an automated trade surveillance system capable of detecting and investigating potential trade practice violations. Such system must maintain all data reflecting the details of each order entered into the trading system or platform, including all order modifications and cancellations, and maintain all data reflecting transactions executed on the swap execution facility. The automated system must load and process daily orders and trades no later than 24 hours after the completion of the trading day. In addition, the automated trade surveillance system must have the capability to detect and flag specific trade execution patterns and trade anomalies; compute, retain, and compare trading statistics; compute trade gains, losses, and futures-equivalent positions; reconstruct the sequence of market activity; perform market analyses; and enable system users to perform in-depth analyses and ad hoc queries of trade-related data.

(e) *Real-time Market Monitoring.* A swap execution facility must conduct real-time market monitoring of all trading activity on its electronic trading platform(s) to ensure orderly trading and identify any market or system anomalies. A swap execution facility must have the authority to adjust trade prices or cancel trades when necessary to mitigate market disrupting events caused by malfunctions in its electronic trading platform(s) or errors in orders submitted by members and market participants. Any trade price

adjustments or trade cancellations must be transparent to the market and subject to standards that are clear, fair, and publicly available.

(f) *Investigations and Investigation Reports.* (1) *Procedures.* A swap execution facility must establish and maintain procedures that require its compliance staff to conduct investigations of possible rule violations. An investigation must be commenced upon the receipt of a request from Commission staff or upon the discovery or receipt of information (such as data produced by automated surveillance systems) by the swap execution facility that, in the judgment of its compliance staff, indicates a possible basis for finding that a violation has occurred or will occur.

(2) *Timeliness.* Each compliance staff investigation must be completed in a timely manner. Absent mitigating factors, a timely manner is no later than 12 months after the date that an investigation is opened. Mitigating factors that may reasonably justify an investigation taking longer than 12 months to complete include the complexity of the investigation, the number of firms or individuals involved as potential wrongdoers, the number of potential violations to be investigated, and the volume of documents and data to be examined and analyzed by compliance staff.

(3) *Investigation reports when a reasonable basis exists for finding a violation.* Compliance staff must submit a written investigation report for disciplinary action in every instance in which compliance staff determines from surveillance or from an investigation that a reasonable basis exists for finding a rule violation. The investigation report must include the reason the investigation was initiated; a summary of the complaint, if any; the relevant facts; compliance staff's analysis and conclusions; and a recommendation as to whether disciplinary action should be pursued. The report must also include the member or market participant's disciplinary history at the swap execution facility, including copies of warning letters.

(4) *Investigation reports when no reasonable basis exists for finding a violation.* If after conducting an investigation compliance staff determines that no reasonable basis exists for finding a violation, it must prepare a written report including the reason the investigation was initiated; a summary of the complaint, if any; the relevant facts; compliance staff's analysis and conclusions; and if applicable, any recommendation that a disciplinary committee issue a warning letter in accordance with § 37.203(f)(5). If compliance staff recommends that a warning letter be issued to a member or market participant pursuant to § 37.203(f)(5), the investigation report must include a copy of the letter as well as the member or market participant's disciplinary history at the swap execution facility, including copies of warning letters.

(5) *Warning letters.* In addition to the action required to be taken under §§ 37.203(f)(3) and 37.203(f)(4), the rules of a swap execution facility may authorize compliance staff to issue a warning letter to a person or entity under investigation or to recommend that a disciplinary committee take such an action. A warning letter issued in accordance with this section is not a penalty or an indication that a finding of a violation has been made. A copy of a warning letter issued by compliance staff must be included in the investigation report required by §§ 37.203(f)(3) and 37.203(f)(4). No more than one warning letter for the same potential violation may be issued to the same person or entity during a rolling 12-month period.

(g) *Additional Rules Required.* A swap execution facility must adopt and enforce any additional rules that it believes are necessary to comply with the requirements of § 37.203.

§ 37.204 Regulatory services provided by a third party.

(a) *Use of third-party provider permitted.* A swap execution facility may choose to contract with a registered futures association or another registered entity, as such terms are defined under the Act, (collectively, "regulatory service provider"), for the provision of services to assist in complying with the core principles, as approved by the Commission. Any swap execution facility that chooses to contract with a regulatory service provider must ensure that its regulatory service provider has the capacity and resources necessary to provide timely and effective regulatory services, including adequate staff and automated surveillance systems. A swap execution facility will at all times remain responsible for the performance of any regulatory services received, for compliance with the swap execution facility's obligations under the Act and Commission regulations, and for the regulatory service provider's performance on its behalf.

(b) *Duty to supervise third party.* A swap execution facility that elects to use the service of a regulatory service provider must retain sufficient compliance staff to supervise the quality and effectiveness of the regulatory services provided on its behalf. Compliance staff of the swap execution facility must hold regular meetings with the regulatory service provider to discuss ongoing investigations, trading patterns, market participants, and any other matters of regulatory concern. A swap execution facility must also conduct periodic reviews of the adequacy and effectiveness of services provided on its behalf. Such reviews must be documented carefully and made available to the Commission upon request.

(c) *Regulatory decisions required from the swap execution facility.* A swap execution facility that elects to use the service of a regulatory service provider must retain exclusive authority in all substantive decisions made by its regulatory service provider, including but not limited to decisions involving the cancellation of trades, the issuance of disciplinary charges against members or market participants, denials of access to the trading platform for disciplinary reasons, and any decision to open an investigation into a possible rule violation. A swap execution facility must document any instances where its actions differ from those recommended by its regulatory service provider.

§ 37.205 Audit trail.

A swap execution facility must establish procedures to capture and retain information that may be used in establishing whether rule violations have occurred.

(a) *Audit Trail Required.* A swap execution facility must capture and retain all audit trail data necessary to detect, investigate and prevent customer and market abuses. Such data must be sufficient to reconstruct all transactions within a reasonable period of time and to provide evidence of any violations of the rules of the swap execution facility. An acceptable audit trail must also permit the swap execution facility to track a customer order from the time of receipt through fill, allocation, or other disposition, and must include both order and trade data.

(b) *Elements of an Acceptable Audit Trail Program.* (1) *Original source documents.* A swap execution facility's audit trail must include original source documents. Original source documents include unalterable, sequentially-identified records on which trade execution information is originally recorded, whether recorded manually or electronically. Records for customer orders (whether filled, unfilled or cancelled, each of which shall be retained or electronically captured) must reflect the terms of the order, a unique account identifier that relates

back to the account(s) owner(s) and the time of order entry. Swap execution facilities that permit intermediation must require that all orders or requests for quotes received by phone that are executable be immediately entered into the trading system or platform. If an order or request for quote cannot be immediately entered into the trading system or platform, an electronic record that includes the account identifier that relates to the account owner, time of receipt, and terms of the order or request for quote must immediately be created, and the order or request for quote must be entered into the trading system or platform as soon as practicable.

(2) *Transaction history database.* A swap execution facility's audit trail program must include an electronic transaction history database. An adequate transaction history database includes a history of all orders and trades, and also includes:

(i) All data that are input into the trade entry or matching system for the transaction to match and clear;

(ii) The categories of participant for which each trade is executed, including whether the person executing a trade was executing it for his/her own account or an account for which he/she has discretion, his/her clearing member's house account, the account of another member or the account of any other customer;

(iii) Timing and sequencing data adequate to reconstruct trading; and

(iv) Identification of each account to which fills are allocated.

(3) *Electronic analysis capability.* A swap execution facility's audit trail program must include electronic analysis capability with respect to all audit trail data in the transaction history database. An adequate electronic analysis capability must permit the sorting and presentation of data in the transaction history database so as to reconstruct trading and identify possible trading violations with respect to both customer and market abuse.

(4) *Safe storage capability.* A swap execution facility's audit trail program must include the capability to safely store all audit trail data retained in its transaction history database. Such safe storage capability must include the capability to store all data in the database in a manner that protects it from unauthorized alteration, as well as from accidental erasure or other loss. Data must be retained in accordance with the recordkeeping requirements of Core Principle 10 for swap execution facilities and the associated regulations in subpart K of this part 37.

(c) *Enforcement of Audit Trail Requirements.* (1) *Annual audit trail and recordkeeping reviews.* A swap execution facility must enforce its audit trail and recordkeeping requirements through at least annual reviews of all members and market participants to verify their compliance with the swap execution facility's audit trail and recordkeeping requirements. Such reviews must include, but are not limited to, reviews of randomly selected samples of front-end audit trail data for order routing systems; a review of the process by which user identifications are assigned and user identification records are maintained; a review of usage patterns associated with user identifications to monitor for violations of user identification rules; and reviews of account numbers and customer type indicator codes in trade records to test for accuracy and improper use.

(2) *Enforcement program required.* A swap execution facility must establish a program for effective enforcement of its audit trail and recordkeeping requirements. An effective program must identify members and market participants that have failed to maintain high levels of compliance with such requirements, and levy meaningful sanctions when deficiencies are found. Sanctions must be sufficient to deter recidivist behavior, and may not include more than one warning letter for the same violation within a rolling twelve month period.

§ 37.206 Disciplinary procedures and sanctions.

A swap execution facility must establish trading, trade processing, and participation rules that will deter abuses and have the capacity to enforce such rules through prompt and effective disciplinary action.

(a) *Enforcement staff.* A swap execution facility must establish and maintain sufficient enforcement staff and resources to effectively and promptly prosecute possible rule violations within the disciplinary jurisdiction of the swap execution facility. A swap execution facility must also monitor the size and workload of its enforcement staff annually, and increase its enforcement resources and staff as appropriate. The enforcement staff may not include either members of the swap execution facility or persons whose interests conflict with their enforcement duties. A member of the enforcement staff may not operate under the direction or control of any person or persons with trading privileges at the swap execution facility. A swap execution facility's enforcement staff may operate as part of the swap execution facility's compliance department.

(b) *Disciplinary panels.* (1) *Disciplinary panels required.* A swap execution facility must establish one or more Review Panels and one or more Hearing Panels (collectively, "disciplinary panels") that are authorized to fulfill their obligations under the rules of this Subpart. Disciplinary panels must meet the composition requirements of § 40.9(c)(3)(ii), and must not include any members of the swap execution facility's compliance staff, or any person involved in adjudicating any other stage of the same proceeding.

(2) *Review panels.* A swap execution facility's Review Panel(s) must be responsible for determining whether a reasonable basis exists for finding a violation of swap execution facility rules, and for authorizing the issuance of notices of charges against persons alleged to have committed violations if the Review Panel believes that the matter should be adjudicated.

(3) *Hearing Panels.* A swap execution facility's Hearing Panel(s) must be responsible for adjudicating disciplinary cases pursuant to a notice of charges authorized by a Review Panel, and must also be responsible for such other duties as are specified in this Subpart.

(c) *Review of investigation report.* Promptly after receiving a completed investigation report pursuant to § 37.203(f)(3), a Review Panel must promptly review the report and, within 30 days of such receipt, must take one of the following actions:

(1) If the Review Panel determines that additional investigation or evidence is needed, it must promptly direct the compliance staff to conduct further investigation.

(2) If the Review Panel determines that no reasonable basis exists for finding a violation or that prosecution is otherwise unwarranted, it may direct that no further action be taken. Such determination must be in writing, and must include a written statement setting forth the facts and analysis supporting the decision.

(3) If the Review Panel determines that a reasonable basis exists for finding a violation and adjudication is warranted, it must direct that the person or entity alleged to have committed the violation be served with a notice of charges and must proceed in accordance with the rules of this section.

(d) *Notice of charges.* A notice of charges must adequately state the acts, conduct, or practices in which the respondent is alleged to have engaged; state the rule, or rules, alleged to have been violated (or about to be violated);

and prescribe the period within which a hearing on the charges may be requested. The notice must also advise the respondent charged that he is entitled, upon request, to a hearing on the charges; and if the rules of the swap execution facility so provide:

(1) The failure to request a hearing within the period prescribed in the notice, except for good cause, may be deemed a waiver of the right to a hearing; and

(2) The failure to answer or to deny expressly a charge may be deemed to be an admission of such charge.

(e) *Right to representation.* Upon being served with a notice of charges, a respondent must have the right to be represented by legal counsel or any other representative of its choosing in all succeeding stages of the disciplinary process.

(f) *Answer to charges.* A respondent must be given a reasonable period of time to file an answer to a notice of charges. The rules of a swap execution facility may require that:

(1) The answer must be in writing and include a statement that the respondent admits, denies, or does not have and is unable to obtain sufficient information to admit or deny each allegation. A statement of a lack of sufficient information shall have the effect of a denial of an allegation;

(2) Failure to file an answer on a timely basis shall be deemed an admission of all allegations contained in the notice of charges; and

(3) Failure in an answer to deny expressly a charge shall be deemed to be an admission of such charge.

(g) *Admission or failure to deny charges.* The rules of a swap execution facility may provide that if a respondent admits or fails to deny any of the charges, a Hearing Panel may find that the violations alleged in the notice of charges for which the respondent admitted or failed to deny any of the charges have been committed. If the swap execution facility's rules so provide, then:

(1) The Hearing Panel must impose a sanction for each violation found to have been committed;

(2) The Hearing Panel must promptly notify the respondent in writing of any sanction to be imposed pursuant to § 37.206(g)(1) and advise the respondent that it may request a hearing on such sanction within a specified period of time;

(3) The rules of a swap execution facility may provide that if a respondent fails to request a hearing within the period of time specified in the notice, the respondent will be deemed to have accepted the sanction.

(h) *Denial of charges and right to hearing.* In every instance where a respondent has requested a hearing on a charge that is denied, or on a sanction set by the Hearing Panel pursuant to Section 37.206(g), the respondent must be given an opportunity for a hearing in accordance with the requirements of § 37.206(j). The swap execution facility's rules may provide that, except for good cause, the hearing must be concerned only with those charges denied and/or sanctions set by the Hearing Panel under § 37.206(g) for which a hearing has been requested.

(i) *Settlement offers.* (1) The rules of a swap execution facility may permit a respondent to submit a written offer of settlement at any time after the investigation report is completed. The disciplinary panel presiding over the matter may accept the offer of settlement, but may not alter the terms of a settlement offer unless the respondent agrees.

(2) The rules of a swap execution facility may provide that, in its discretion, a disciplinary panel may permit the respondent to accept a sanction without either admitting or denying the rule violations upon which the sanction is based.

(3) If an offer of settlement is accepted, the panel accepting the offer must issue a written decision specifying the rule violations it has reason to believe were committed, including the basis or reasons for the panel's conclusions, and any sanction to be imposed, which must include full customer restitution where customer harm is demonstrated. If an offer of settlement is accepted without the agreement of the enforcement staff, the decision must adequately support the Hearing Panel's acceptance of the settlement. Where applicable, the decision must also include a statement that the respondent has accepted the sanctions imposed without either admitting or denying the rule violations.

(4) The respondent may withdraw his or her offer of settlement at any time before final acceptance by a panel. If an offer is withdrawn after submission, or is rejected by a disciplinary panel, the respondent must not be deemed to have made any admissions by reason of the offer of settlement and must not be otherwise prejudiced by having submitted the offer of settlement.

(j) *Hearings.* (1) A swap execution facility must adopt rules that provide for the following minimum requirements for any hearing conducted pursuant to a notice of charges:

(i) The hearing must be fair, must be conducted before members of the Hearing Panel, and must be promptly convened after reasonable notice to the respondent. The formal rules of evidence need not apply; nevertheless, the procedures for the hearing may not be so informal as to deny a fair hearing. No member of the Hearing Panel for the matter may have a financial, personal, or other direct interest in the matter under consideration.

(ii) In advance of the hearing, the respondent must be entitled to examine all books, documents, or other evidence in the possession or under the control of the swap execution facility that are to be relied upon by the enforcement staff in presenting the charges contained in the notice of charges or that are relevant to those charges.

(iii) The swap execution facility's enforcement and compliance staffs must be parties to the hearing, and the enforcement staff must present their case on those charges and sanctions that are the subject of the hearing.

(iv) The respondent must be entitled to appear personally at the hearing, must be entitled to cross-examine any persons appearing as witnesses at the hearing, and must be entitled to call witnesses and to present such evidence as may be relevant to the charges.

(v) The swap execution facility must require that persons within its jurisdiction who are called as witnesses participate in the hearing and produce evidence. It must make reasonable efforts to secure the presence of all other persons called as witnesses whose testimony would be relevant.

(vi) If the respondent has requested a hearing, a copy of the hearing must be made and must become a part of the record of the proceeding. The record must be one that is capable of being accurately transcribed; however, it need not be transcribed unless the transcript is requested by Commission staff or the respondent, the decision is appealed pursuant to § 37.206(l), or is reviewed by the Commission pursuant to Section 8c of the Act or part 9 of this chapter. In all other instances, a summary record of a hearing is permitted.

(vii) The rules of a swap execution facility may provide that the cost of transcribing the record of the hearing must be borne by a respondent who requests the transcript, appeals the decision pursuant to § 37.206(l), or whose application for Commission review of the disciplinary action has been granted. In all other instances, the cost of transcribing the record must be borne by the swap execution facility.

(2) The rules of a swap execution facility may provide that a sanction may be summarily imposed upon any person within its jurisdiction whose actions impede the progress of a hearing.

(k) *Decisions.* Promptly following a hearing conducted in accordance with § 37.206(j), the Hearing Panel must render a written decision based upon the weight of the evidence contained in the record of the proceeding and must provide a copy to the respondent. The decision must include:

(1) The notice of charges or a summary of the charges;

(2) The answer, if any, or a summary of the answer;

(3) A summary of the evidence produced at the hearing or, where appropriate, incorporation by reference of the investigation report;

(4) A statement of findings and conclusions with respect to each charge, and a complete explanation of the evidentiary and other basis for such findings and conclusions with respect to each charge;

(5) An indication of each specific rule that the respondent was found to have violated;

(6) A declaration of all sanctions imposed against the respondent, including the basis for such sanctions and the effective date of such sanctions.

(l) *Right to appeal.* The rules of a swap execution facility may permit the parties to a proceeding to appeal promptly an adverse decision of the Hearing Panel in all or in certain classes of cases. Such rules may require a party's notice of appeal to be in writing and to specify the findings, conclusions, or sanctions to which objection are taken. If the rules of a swap execution facility permit appeals, then both the respondent and the enforcement staff must have the opportunity to appeal and the swap execution facility must provide for the following:

(1) The swap execution facility must establish an appellate panel that must be authorized to hear appeals of respondents. In addition, the rules of a swap execution facility may provide that the appellate panel may, on its own initiative, order review of a decision by the Hearing Panel within a reasonable period of time after the decision has been rendered.

(2) The composition of the appellate panel must be consistent with § 40.9(c)(iv), and must not include any members of the swap execution facility's compliance staff, or any person involved in adjudicating any other stage of the same proceeding. The rules of a swap execution facility must provide for the appeal proceeding to be conducted before all of the members of the board of appeals or a panel thereof.

(3) Except for good cause shown, the appeal or review must be conducted solely on the record before the Hearing Panel, the written exceptions filed by the parties, and the oral or written arguments of the parties.

(4) Promptly following the appeal or review proceeding, the board of appeals must issue a written decision and must provide a copy to the respondent. The decision issued by the board of appeals must adhere to all the requirement of § 37.206(k), to the extent that a different conclusion is reached from that issued by the Hearing Panel.

(m) *Final decisions.* Each swap execution facility must establish rules setting forth when a decision rendered pursuant to this section will become the final decision of such swap execution facility.

(n) *Disciplinary sanctions.* All disciplinary sanctions imposed by a swap execution facility or its disciplinary panels must be commensurate with the violations committed and must be clearly sufficient to deter recidivism or similar violations by other market participants. All disciplinary sanctions must take into account the respondent's disciplinary history. In the event of demonstrated customer harm, any disciplinary sanction must also include full customer restitution.

(o) *Summary fines for violations of rules regarding timely submission of records.* A swap execution facility may adopt a summary fine schedule for violations of rules relating to the timely submission of accurate records required for clearing or verifying each day's transactions. A swap execution facility may permit its compliance staff, or a designated panel of swap execution facility officials, to summarily impose minor sanctions against persons within the swap execution facility's jurisdiction for violating such rules. A swap execution facility's summary fine schedule may allow for warning letters to be issued for first-time violations or violators, provided that no more than one warning letter may be issued per rolling 12-month period for the same violation. If adopted, a summary fine schedule must provide for progressively larger fines for recurring violations.

(p) *Emergency disciplinary actions.* (1) A swap execution facility may impose a sanction, including suspension, or take other summary action against a person or entity subject to its jurisdiction upon a reasonable belief that such immediate action is necessary to protect the best interest of the marketplace.

(2) Any emergency disciplinary action must be taken in accordance with a swap execution facility's procedures that provide for the following:

(i) If practicable, a respondent must be served with a notice before the action is taken, or otherwise at the earliest possible opportunity. The notice must state the action, briefly state the reasons for the action, and state the effective time and date, and the duration of the action.

(ii) The respondent must have the right to be represented by legal counsel or any other representative of its choosing in all proceedings subsequent to the emergency action taken. The respondent must be given the opportunity for a hearing as soon as reasonably practicable and the hearing must be conducted before the Hearing Panel pursuant to the requirements of § 37.206(j).

(iii) Promptly following the hearing provided for in this rule, the swap execution facility must render a written decision based upon the weight of the evidence contained in the record of the proceeding and must provide a copy to the respondent. The decision must include a description of the summary action taken; the reasons for the summary action; a summary of the evidence produced at the hearing; a statement of findings and conclusions; a determination that the summary action should be affirmed, modified, or reversed; and a declaration of any action to be taken pursuant to the determination, and the effective date and duration of such action.

§ 37.207 Swaps subject to mandatory clearing.

A swap execution facility shall provide by its rules that when a swap dealer or major swap participant enters into or facilitates a swap transaction that is subject to the mandatory clearing requirement of Section 2(h) of the Act, the swap dealer or major swap participant shall be responsible for compliance with the mandatory trading requirement under Section 2(h)(8).

Subpart D—Swaps Not Readily Susceptible to Manipulation

§ 37.300 Core Principle 3—Swaps not readily susceptible to manipulation.

The swap execution facility shall permit trading only in swaps that are not readily susceptible to manipulation.

§ 37.301 General requirement.

(a) To demonstrate to the Commission compliance with the requirements of § 37.300, a swap execution facility must submit new swap contracts in advance to the Commission pursuant to part 40 of this chapter, either by:

(1) Requesting prior approval from the Commission; or

(2) Self-certification for new product submissions.

(b) Furthermore, the swap execution facility must provide evidence that the swap complies with Core Principle 3 by providing the applicable information as set forth in appendix C to part 38—Demonstration of Compliance that a contract is not readily susceptible to manipulation.

Subpart E—Monitoring of Trading and Trade Processing

§ 37.400 Core Principle 4—Monitoring of trading and trade processing.

The swap execution facility shall:

(a) Establish and enforce rules or terms and conditions defining, or specifications detailing:

(1) Trading procedures to be used in entering and executing orders traded on or through the facilities of the swap execution facility; and

(2) Procedures for trade processing of swaps on or through the facilities of the swap execution facility; and

(b) Monitor trading in swaps to prevent manipulation, price distortion, and disruptions of the delivery or cash settlement process through surveillance, compliance, and disciplinary practices and procedures, including methods for conducting real-time monitoring of trading and comprehensive and accurate trade reconstructions.

§ 37.401 General requirements.

A swap execution facility must:

(a) Collect and evaluate data on individual traders' market activity on an ongoing basis in order to detect and prevent manipulation, price distortions and, where possible, disruptions of the delivery or cash-settlement process;

(b) Monitor and evaluate general market data in order to detect and prevent manipulative activity that would result in the failure of the market price to reflect the normal forces of supply and demand;

(c) Have the capacity to conduct real-time monitoring of trading and comprehensive and accurate trade reconstruction. The monitoring of intraday trading must include the capacity to detect abnormal price movements, unusual trading volumes, impairments to market liquidity, and position-limit violations; and

(d) Have either manual processes or automated alerts that are effective in detecting and preventing trading abuses.

§ 37.402 Additional requirements for physical-delivery swaps.

(a) For physical-delivery swaps, the swap execution facility must:

(1) Monitor a swap's terms and conditions;

(2) Monitor that the deliverable supply is adequate so that the swap will not be conducive to price manipulation or distortion;

(3) Assess whether the deliverable commodity reasonably can be expected to be available to traders responsible for making the delivery and salable or usable by traders receiving delivery at its market value in normal cash marketing channels; and

(4) When available, monitor data related to the size and ownership of deliverable supplies.

(b) The swap execution facility must continually monitor the appropriateness of the swap's terms and conditions, including the delivery instrument, the delivery locations and location differentials, and the commodity characteristics and related differentials. The swap execution facility must act promptly to address the conditions that are causing price distortions or market disruptions, including, when appropriate, changes to contract terms.

§ 37.403 Additional requirements for cash-settled swaps.

(a) For cash-settled swaps, the swap execution facility must monitor:

(1) The availability and pricing of the commodity making up the index to which the swap will be settled; and

(2) The continued appropriateness of the methodology for deriving the index. For those swap execution facilities that compute their own indices, they must promptly amend any methodologies that result, or are likely to result, in manipulation, price distortions, or market disruptions, or must impose new methodologies to resolve the threat of disruptions or distortions.

(b) If a swap listed on a swap execution facility is settled by reference to the price of a swap traded in another venue, including a price or index derived from prices on another swap execution facility, the swap execution facility must have an information sharing agreement with the other venue or swap execution facility. In lieu of an information sharing agreement, the swap execution facility must have the capacity to assess whether positions or trading in the swap or commodity to which its swap is cash-settled are being manipulated in order to affect prices on its market.

§ 37.404 Ability to obtain information.

(a) The swap execution facility must have rules that require traders in its swaps to keep records of their trading, including records of their activity in the underlying commodity and related derivatives markets and make such records available, upon request, to the swap execution facility and the Commission.

(b) A swap execution facility with customers trading through intermediaries must either use a comprehensive large-trader reporting system (LTRS) or be able to demonstrate that it can obtain position data from other sources in order to conduct an effective surveillance program.

§ 37.405 Risk controls for trading.

The swap execution facility must establish and maintain risk control mechanisms to reduce the potential risk of market disruptions, including but not limited to market restrictions that pause or halt trading in market conditions prescribed by the swap execution facility. If a swap is linked to, or a substitute for, other swaps on the swap execution facility or on other trading venues, such risk controls must, to the extent practicable, be coordinated with any similar controls placed on those other swaps. If a swap is based on the level of an equity index, such risk controls must, to the extent practicable, be coordinated with any similar controls placed on national security exchanges.

§ 37.406 Trade reconstruction.

The swap execution facility must have the ability to comprehensively and accurately reconstruct all trading on its trading facility. All audit-trail data and reconstructions must be made available to the Commission in a form, manner, and time as determined by the Commission.

§ 37.407 Additional rules required.

A swap execution facility must adopt and enforce any additional rules that it believes are necessary to comply with the requirements of subpart E of this part.

Subpart F—Ability To Obtain Information

§ 37.500 Core Principle 5—Ability To Obtain Information.

The swap execution facility shall:

(a) Establish and enforce rules that will allow the facility to obtain any necessary information to perform any of the functions described in this section;

(b) Provide the information to the Commission on request; and

(c) Have the capacity to carry out such international information-sharing agreements as the Commission may require.

§ 37.501 Establish and enforce rules.

A swap execution facility must establish and enforce rules that will allow the swap execution facility to have the ability and authority to obtain sufficient information to allow it to fully perform its operational, risk

management, governance, and regulatory functions and any requirements under this part 37, including the capacity to carry out international information-sharing agreements as the Commission may require.

§ 37.502 Collection of information.

A swap execution facility must have rules that allow it to collect information on a routine basis, allow for the collection of non-routine data from its participants, and allow for its examination of books and records kept by the traders on its facility.

§ 37.503 Provide information to the Commission.

A swap execution facility shall provide information in its possession to the Commission upon request, in a form and manner that the Commission approves.

§ 37.504 Information-sharing agreements.

A swap execution facility shall share information with other regulatory organizations, data repositories, and reporting services as required by the Commission or as otherwise necessary and appropriate to fulfill its self-regulatory and reporting responsibilities. Appropriate information-sharing agreements can be established with such entities or the Commission can act in conjunction with the swap execution facility to carry out such Information Sharing.

Subpart G—Position Limits or Accountability

§ 37.600 Core Principle 6—Position limits or accountability.

(a) *In general.* To reduce the potential threat of market manipulation or congestion, especially during trading in the delivery month, a swap execution facility that is a trading facility shall adopt for each of the contracts of the facility, as is necessary and appropriate, position limitations or position accountability for speculators.

(b) *Position limits.* For any contract that is subject to a position limitation established by the Commission pursuant to Section 4a(a) of the Act, the swap execution facility shall:

(1) Set its position limitation at a level no higher than the Commission limitation; and

(2) Monitor positions established on or through the swap execution facility for compliance with the limit set by the Commission and the limit, if any, set by the swap execution facility.

§ 37.601 Position limits or accountability.

(a) To reduce the potential threat of market manipulation or congestion, especially during trading in the delivery month, a swap execution facility that is a trading facility shall adopt for each of the contracts on the facility, as is necessary and appropriate, position limitations or position accountability for speculators.

(b) For any contract that is subject to a position limitation established by the Commission pursuant to Section 4a(a), the swap execution facility shall:

(1) Set its position limitation at a level no higher than the Commission limitation;

(2) Monitor positions established on or through the swap execution facility for compliance with the limit set by the Commission and the limit, if any, set by the swap execution facility.

(c) The swap execution facility must establish the position limits in accordance with the requirements set forth in part 151.

Subpart H—Financial Integrity of Transactions

§ 37.700 Core Principle 7—Financial integrity of transactions.

The swap execution facility shall establish and enforce rules and procedures for ensuring the financial integrity of swaps entered on or through the facilities of the swap execution facility, including the clearance and settlement of the swaps pursuant to Section 2(h)(1) of the Act.

§ 37.701 Mandatory clearing.

Transactions executed on or through the swap execution facility must be cleared through a Commission-registered derivatives clearing organization unless:

(a) The transaction is exempted from clearing under Section 2(h)(7) of the Act; or

(b) The Commission has not determined that the clearing requirement under Section 2(h)(1) is applicable.

§ 37.702 General financial integrity.

A swap execution facility must provide for the financial integrity of its transactions:

(a) By establishing minimum financial standards for its members, which shall, at a minimum, require that members qualify as an eligible contract participant as defined in Section 1a (18) of the Act;

(b) For transactions cleared by a derivatives clearing organization, by ensuring that the swap execution facility has the capacity to route transactions to the derivative clearing organization in a manner acceptable to the derivatives clearing organization for purposes of ongoing risk management;

(c) For transactions not cleared by a derivatives clearing organization, by requiring members to demonstrate that they:

(1) Have entered into credit arrangement documentation for the transaction;

(2) Have the ability to exchange collateral; and

(3) Meet any credit filters that may be adopted by the swap execution facility; and

(d) By implementing any additional safeguards as may be required by Commission regulations.

§ 37.703 Monitoring for financial soundness.

A swap execution facility must monitor members' compliance with the swap execution facility's minimum financial standards and, therefore, must routinely receive and promptly review financial and related information from its members.

Subpart I—Emergency Authority

§ 37.800 Core Principle 8—Emergency authority.

The swap execution facility shall adopt rules to provide for the exercise of emergency authority, in consultation or cooperation with the Commission, as is necessary and appropriate, including the authority to liquidate or transfer open positions in any swap or to suspend or curtail trading in a swap.

§ 37.801 Additional sources for compliance.

Applicants and swap execution facilities may refer to the guidance and/or acceptable practices in appendix B to part 37 to demonstrate to the Commission compliance with the requirements of § 37.800.

Subpart J—Timely Publication of Trading Information

§ 37.900 Core Principle 9—Timely publication of trading information.

(a) *In general.* The swap execution facility shall make public timely information on price, trading volume, and other trading data on swaps to the extent prescribed by the Commission.

(b) *Capacity of swap execution facility.* The swap execution facility shall be required to have the capacity to electronically capture and transmit trade information with respect to transactions executed on the facility.

§ 37.901 General requirement.

With respect to swaps traded on or through a swap execution facility, each swap execution facility must:

(a) Report specified swap data as provided under part 43 and part 45 of this Chapter; and

(b) Meet the requirements of part 16 of this chapter.

§ 37.902 Capacity of swap execution facility.

The swap execution facility must have the capacity to electronically capture trade information with respect to transactions executed on the facility.

Subpart K—Recordkeeping and Reporting

§ 37.1000 Core Principle 10—Recordkeeping and reporting.

(a) *In general.* A swap execution facility shall:

(1) Maintain records of all activities relating to the business of the facility, including a complete audit trail, in a form and manner acceptable to the Commission for a period of 5 years;

(2) Report to the Commission, in a form and manner acceptable to the Commission, such information as the Commission determines to be necessary or appropriate for the Commission to perform the duties of the Commission under the Act; and

(3) Keep any such records relating to swaps defined in Section 1a(47)(A)(v) of the Act open to inspection and examination by the Securities and Exchange Commission.

(b) *Requirements.* The Commission shall adopt data collection and reporting requirements for swap execution facilities that are comparable to corresponding requirements for derivatives clearing organizations and swap data repositories.

§ 37.1001 Recordkeeping required.

A swap execution facility must maintain records of all activities relating to the business of the facility, in a form and manner acceptable to the Commission, for a period of at least 5 years. A swap execution facility must maintain such records, including a complete audit trail for all swaps executed on or subject to the rules of the swap execution facility, investigatory files, and disciplinary files, in accordance with the requirements of § 1.31 and part 45 of this chapter.

§ 37.1002 Reporting to the commission required.

A swap execution facility must report to the Commission, in a form and manner acceptable to the Commission, such information as the Commission determines to be necessary or appropriate for the Commission to perform its duties under the Act.

§ 37.1003 Inspection and examination by the Securities and Exchange Commission.

A swap execution facility must keep any such records relating to swaps defined in Section 1a(47)(A)(v) of the Act open to inspection and examination by the Securities and Exchange Commission.

Subpart L—Antitrust Considerations

§ 37.1100 Core Principle 11—Antitrust considerations.

Unless necessary or appropriate to achieve the purposes of this Act, the swap execution facility shall not:

(a) Adopt any rules or take any actions that result in any unreasonable restraint of trade; or

(b) Impose any material anticompetitive burden on trading or clearing.

§ 37.1101 Additional sources for compliance.

Applicants and swap execution facilities may refer to the guidance and/or acceptable practices in appendix B to part 37 to demonstrate to the Commission compliance with the requirements of § 37.1100.

Subpart M—Conflicts of Interest

§ 37.1200 Core Principle 12—Conflicts of interest.

The swap execution facility shall:

(a) Establish and enforce rules to minimize conflicts of interest in its decision-making process; and

(b) Establish a process for resolving the conflicts of interest.

Subpart N—Financial Resources

§ 37.1300 Core Principle 13—Financial resources.

(a) *In general.* The swap execution facility shall have adequate financial, operational, and managerial resources to discharge each responsibility of the swap execution facility.

(b) *Determination of resource adequacy.* The financial resources of a swap execution facility shall be considered to be adequate if the value of the financial resources exceeds the total amount that would enable the swap execution facility to cover the operating costs of the swap execution facility for a one-year period, as calculated on a rolling basis.

§ 37.1301 General requirements.

(a) A swap execution facility shall maintain financial resources sufficient to enable it to perform its functions in compliance with the core principles set forth in Section 5h of the Act.

(b) An entity that operates as both a swap execution facility and a derivatives clearing organization also shall comply with the financial resource requirements of § 39.11.

(c) Financial resources shall be considered sufficient if their value is at least equal to a total amount that would enable the swap execution facility, or applicant for designation as such, to cover its operating costs for a period of at least one year, calculated on a rolling basis.

§ 37.1302 Types of financial resources.

Financial resources available to satisfy the requirements of § 37.1301 may include:

(a) The swap execution facility's own capital; and

(b) Any other financial resource deemed acceptable by the Commission.

§ 37.1303 Computation of financial resource requirement.

A swap execution facility shall, on a quarterly basis, based upon its fiscal year, make a reasonable calculation of its projected operating costs over a twelve-month period in order to determine the amount needed to meet the requirements of § 37.1301. The swap execution facility shall have reasonable discretion in determining the methodology used to compute such projected operating costs. The Commission may review the methodology and require changes as appropriate.

§ 37.1304 Valuation of financial resources.

At appropriate intervals, but not less than quarterly, a swap execution facility shall compute the current market value of each financial resource used to meet its obligations under § 37.701. Reductions in value to reflect market and credit risk (haircuts) shall be applied as appropriate.

§ 37.1305 Liquidity of financial resources.

The financial resources allocated by the swap execution facility to meet the requirements of § 37.1301 must include unencumbered, liquid financial assets (*i.e.,* cash and/or highly liquid securities) equal to at least six months' operating costs. If any portion of such financial resources is not sufficiently liquid, the swap execution facility may take into account a committed line of credit or similar facility for the purpose of meeting this requirement.

§ 37.1306 Reporting requirements.

(a) Each fiscal quarter, or at any time upon Commission request, a swap execution facility shall:

(1) Report to the Commission:

(i) The amount of financial resources necessary to meet the requirements of § 37.1301; and

(ii) The value of each financial resource available, computed in accordance with the requirements of § 37.1304;

(2) Provide the Commission with a financial statement, including the balance sheet, income statement, and statement of cash flows of the swap execution facility or of its parent company;

(b) The calculations required by this § 37.1306 shall be made as of the last business day of the swap execution facility's fiscal quarter.

(c) The swap execution facility shall provide the Commission with:

(1) Sufficient documentation explaining the methodology used to compute its financial requirements under § 37.1301;

(2) Sufficient documentation explaining the basis for its determinations regarding the valuation and liquidity requirements set forth in §§ 37.1304 and 37.1305; and

(3) Copies of any agreements establishing or amending a credit facility, insurance coverage, or other arrangement evidencing or otherwise supporting the swap execution facility's conclusions.

(d) The report required by this § 37.1306 shall be filed not later than 17 business days after the end of the swap execution facility's fiscal quarter, or at such later time as the Commission may permit, in its discretion, upon request by the swap execution facility.

Subpart O—System Safeguards

§ 37.1400 Core Principle 14—System safeguards.

The swap execution facility shall:

(a) Establish and maintain a program of risk analysis and oversight to identify and minimize sources of operational risk, through the development of appropriate controls and procedures, and automated systems, that:

(1) Are reliable and secure; and

(2) Have adequate scalable capacity;

(b) Establish and maintain emergency procedures, backup facilities, and a plan for disaster recovery that allow for:

(1) The timely recovery and resumption of operations; and

(2) The fulfillment of the responsibilities and obligations of the swap execution facility; and

(c) Periodically conduct tests to verify that the backup resources of the swap execution facility are sufficient to ensure continued:

(1) Order processing and trade matching;

(2) Price reporting;

(3) Market surveillance; and

(4) Maintenance of a comprehensive and accurate audit trail.

§ 37.1401 Requirements.

(a) Each swap execution facility shall:

(1) Establish and maintain a program of risk analysis and oversight to identify and minimize sources of operational risk through the development of appropriate controls and procedures and the development of automated systems that are reliable, secure, and have adequate scalable capacity;

(2) Establish and maintain emergency procedures, backup facilities, and a plan for disaster recovery that allow for the timely recovery and resumption of operations and the fulfillment of the responsibilities and obligations of the swap execution facility; and

(3) Periodically conduct tests to verify that backup resources are sufficient to ensure continued order processing and trade matching, transmission of matched orders to a designated clearing organization for clearing, price reporting, market surveillance, and maintenance of a comprehensive and accurate audit trail.

(b) A swap execution facility's program of risk analysis and oversight with respect to its operations and automated systems must address each of the following categories of risk analysis and oversight:

(1) Information security;

(2) Business continuity-disaster recovery ("BC–DR") planning and resources;

(3) Capacity and performance planning;

(4) Systems operations;

(5) Systems development and quality assurance; and

(6) Physical security and environmental controls.

(c) In addressing the categories of risk analysis and oversight required under paragraph (b) of this section, a swap execution facility should follow generally accepted standards and best practices with respect to the development, operation, reliability, security, and capacity of automated systems.

(d) A swap execution facility must maintain a BC–DR plan and BC–DR resources, emergency procedures, and backup facilities sufficient to enable timely recovery and resumption of its operations and resumption of its ongoing fulfillment of its responsibilities and obligations as a swap execution facility following any disruption of its operations. Such responsibilities and obligations include, without limitation, order processing and trade matching; transmission of matched orders to a designated clearing organization for clearing, where appropriate; price reporting; market surveillance; and maintenance of a comprehensive audit trail. The swap execution facility's BC–DR plan and resources generally should enable resumption of trading and clearing of swaps executed on the swap execution facility during the next business day following the disruption. Swap execution facilities determined by the Commission to be critical financial markets are subject to more stringent requirements in this regard, set forth in Section 40.9 of the Commission's regulations.

(e) A swap execution facility that is not determined by the Commission to be a critical financial market satisfies the requirement to be able to resume trading and clearing during the next business day following a disruption by maintaining either:

(1) Infrastructure and personnel resources of its own that are sufficient to ensure timely recovery and resumption of its operations and resumption of its ongoing fulfillment of its responsibilities and obligations as a swap execution facility following any disruption of its operations; or

(2) Contractual arrangements with other swap execution facilities or disaster recovery service providers, as appropriate, that are sufficient to ensure continued trading and clearing of swaps executed on the swap execution facility, and ongoing fulfillment of all of the swap execution facility's responsibilities and obligations with respect to such swaps, in the event that a disruption renders the swap execution facility temporarily or permanently unable to satisfy this requirement on its own behalf.

(f) A swap execution facility must notify Commission staff promptly of all:

(1) Electronic trading halts and systems malfunctions;

(2) Cyber security incidents or targeted threats that actually or potentially jeopardize automated system operation, reliability, security, or capacity; and

(3) Any activation of the swap execution facility's BC–DR plan.

(g) A swap execution facility must give Commission staff timely advance notice of all:

(1) Planned changes to automated systems that may impact the reliability, security, or adequate scalable capacity of such systems; and

(2) Planned changes to the swap execution facility's program of risk analysis and oversight.

(h) A swap execution facility must provide to the Commission upon request current copies of its BC–DR plan and other emergency procedures, its assessments of its operational risks, and other documents requested by Commission staff for the purpose of maintaining a current profile of the swap execution facility's automated systems.

(i) A swap execution facility must conduct regular, periodic, objective testing and review of its automated systems to ensure that they are reliable, secure, and have adequate scalable capacity. It must also conduct regular, periodic testing and review of its BC–DR capabilities. Both types of testing should be conducted by qualified, independent professionals. Such qualified independent professionals may be independent contractors or employees of the swap execution facility, but should not be persons responsible for development or operation of the systems or capabilities being tested. Pursuant to Core Principle 10 under Section 5h of the Act (Recordkeeping and Reporting), and §§ 37.1000 through 37.1003, the swap execution facility must keep records of all such tests, and make all test results available to the Commission upon request.

(j) To the extent practicable, a swap execution facility should:

(1) Coordinate its BC–DR plan with those of the market participants upon whom it depends to provide liquidity, in a manner adequate to enable effective resumption of activity in its markets following a disruption causing activation of the swap execution facility's BC–DR plan;

(2) Initiate and coordinate periodic, synchronized testing of its BC–DR plan and the BC–DR plans of the market participants upon whom it depends to provide liquidity; and

(3) Ensure that its BC–DR plan takes into account the BC–DR plans of its telecommunications, power, water, and other essential service providers.

(k) Part 46 of this chapter governs the obligations of those registered entities that the Commission has determined to be critical financial markets, with respect to maintenance and geographic dispersal of disaster recovery resources sufficient to meet a same-day recovery time objective in the event of a wide-scale disruption. Section 40.9 establishes the requirements for core principle compliance in that respect.

Subpart P—Designation of Chief Compliance Officer

§ 37.1500 Core Principle 15—Designation of Chief Compliance Officer.

(a) *In general.* Each swap execution facility shall designate an individual to serve as a chief compliance officer.

(b) *Duties.* The chief compliance officer shall:

(1) Report directly to the board or to the senior officer of the facility;

(2) Review compliance with the core principles in this subsection;

(3) In consultation with the board of the facility, a body performing a function similar to that of a board, or the senior officer of the facility, resolve any conflicts of interest that may arise;

(4) Be responsible for establishing and administering the policies and procedures required to be established pursuant to this section;

(5) Ensure compliance with the Act and the rules and regulations issued under the Act, including rules prescribed by the Commission pursuant to this section; and

(6) Establish procedures for the remediation of noncompliance issues found during compliance office reviews, look backs, internal or external audit findings, self-reported errors, or through validated complaints.

(c) *Requirements for procedures.* In establishing procedures under paragraph (b)(6) of this section, the chief compliance officer shall design the procedures to establish the handling, management response, remediation, retesting, and closing of noncompliance issues.

(d) *Annual reports.* (1) *In general.* In accordance with rules prescribed by the Commission, the chief compliance officer shall annually prepare and sign a report that contains a description of:

(i) The compliance of the swap execution facility with the Act; and

(ii) The policies and procedures, including the code of ethics and conflict of interest policies, of the swap execution facility.

(2) *Requirements.* The chief compliance officer shall:

(i) Submit each report described in clause (1) with the appropriate financial report of the swap execution facility that is required to be submitted to the Commission pursuant to this section; and

(ii) Include in the report a certification that, under penalty of law, the report is accurate and complete.

§ 37.1501 Chief Compliance Officer.

(a) *Definition of Board of Directors.* For purposes of this part 37, the term "board of directors" means the board of directors of a registered swap execution facility, or for those swap execution facilities whose organizational structure does not include a board of directors, a body performing a function similar to a board of directors.

(b) *Designation and qualifications of chief compliance officer.*

(1) *Chief Compliance Officer Required.* Each registered swap execution facility shall establish the position of chief compliance officer, and designate an individual to serve in that capacity.

(i) The position of chief compliance officer shall carry with it the authority and resources to develop and enforce policies and procedures necessary to fulfill the duties set forth for chief compliance officers in the Act and Commission regulations.

(ii) The chief compliance officer shall have supervisory authority over all staff acting in furtherance of the chief compliance officer's statutory, regulatory, and self-regulatory obligations.

(2) *Qualifications of Chief Compliance Officer.* The individual designated to serve as chief compliance officer shall have the background and skills appropriate for fulfilling the responsibilities of the position.

(i) No individual disqualified from registration pursuant to Sections 8a(2) or 8a(3) of the Act may serve as a chief compliance officer.

(ii) The chief compliance officer may not be a member of the swap execution facility's legal department and may not serve as its general counsel.

(c) *Appointment, Supervision, and Removal of Chief Compliance Officer.*

(1) *Appointment and Compensation of Chief Compliance Officer Determined by Board of Directors.* A registered swap execution facility's chief compliance officer shall be appointed by its board of directors. The board of directors must also approve the compensation of the chief compliance officer and shall meet with the chief compliance officer at least annually. The chief compliance officer shall also meet with the regulatory oversight committee, as defined in § 37.19(b), at least quarterly. The chief compliance officer shall provide any information regarding the swap execution facility's regulatory program that is requested by the board of directors or the regulatory oversight committee. The appointment of the chief compliance officer and approval of the chief compliance officer's compensation shall require the approval of a majority of the board of directors. The senior officer of the swap execution facility may fulfill these responsibilities. A swap execution facility shall notify

the Commission of the appointment of a new chief compliance officer within two business days of such appointment.

(2) *Supervision of Chief Compliance Officer.* A swap execution facility's chief compliance officer shall report directly to the board of directors or to the senior officer of the swap execution facility, at the swap execution facility's discretion.

(3) *Removal of Chief Compliance Officer by Board of Directors.* Removal of a registered swap execution facility's chief compliance officer shall require the approval of a majority of the swap execution facility's board of directors. If the swap execution facility does not have a board of directors, then the chief compliance officer may be removed by the senior officer of the swap execution facility. The swap execution facility shall notify the Commission and explain the reasons for the departure within two business days. The swap execution facility shall immediately appoint an interim chief compliance officer, and shall appoint a permanent chief compliance officer as soon as reasonably practicable. The swap execution facility shall notify the Commission within two business days of appointing any new chief compliance officer, whether interim or permanent.

(d) *Duties of Chief Compliance Officer.* The chief compliance officer's duties shall include, but are not limited to, the following:

(1) Overseeing and reviewing the swap execution facility's compliance with Section 5h of the Act and any related rules adopted by the Commission;

(2) In consultation with the board of directors, a body performing a function similar to the board, or the senior officer of the swap execution facility, resolving any conflicts of interest that may arise:

(i) Conflicts between business considerations and compliance requirements;

(ii) Conflicts between business considerations and the requirement that the registered swap execution facility provide fair, open, and impartial access as set forth in § 37.202 of this part; and;

(iii) Conflicts between a registered swap execution facility's management and members of the board of directors;

(3) Establishing and administering written policies and procedures reasonably designed to prevent violation of the Act and any rules adopted by the Commission;

(4) Ensuring compliance with the Act and Commission regulations relating to agreements, contracts, or transactions, and with Commission regulations under Section 5h of the Act;

(5) Establishing procedures for the remediation of noncompliance issues identified by the chief compliance officer through a compliance office review, look-back, internal or external audit finding, self-reported error, or validated complaint;

(6) Establishing and following appropriate procedures for the handling, management response, remediation, retesting, and closing of noncompliance issues;

(7) Establishing a compliance manual designed to promote compliance with the applicable laws, rules, and regulations and administering a written code of ethics designed to prevent ethical violations and to promote honesty and ethical conduct;

(8) Supervising the swap execution facility's self-regulatory program with respect to trade practice surveillance; market surveillance; real-time market monitoring; compliance with audit trail requirements; enforcement and disciplinary proceedings; audits, examinations, and other regulatory responsibilities with respect to members and market participants (including ensuring compliance with, if applicable, financial integrity, financial reporting, sales practice, recordkeeping, and other requirements); and

(9) Supervising the effectiveness and sufficiency of any regulatory services provided to the swap execution facility by a registered futures association or other registered entity in accordance with § 37.204.

(e) *Annual Compliance Report Prepared by Chief Compliance Officer.* The chief compliance officer shall, not less than annually, prepare an annual compliance report, that at a minimum, contains the following information covering the time period since the date on which the swap execution facility became registered with the Commission or since the end of the period covered by a previously filed annual compliance report, as applicable:

(1) A description of the registered swap execution facility's written policies and procedures, including the code of ethics and conflict of interest policies;

(2) A review of applicable Commission regulations and each subsection and core principle of Section 5h of the Act, that, with respect to each:

(i) Identifies the policies and procedures that ensure compliance with each subsection and the core principle, including each duty specified in Section 5h(f)(15)(B);

(ii) Provides a self-assessment as to the effectiveness of these policies and procedures; and

(iii) Discusses areas for improvement, and recommends potential or prospective changes or improvements to its compliance program and resources;

(3) A list of any material changes to compliance policies and procedures since the last annual compliance report;

(4) A description of the financial, managerial, and operational resources set aside for compliance with respect to the Act and Commission regulations, including a description of the registered swap execution facility's self-regulatory program's staffing and structure, a catalogue of investigations and disciplinary actions taken since the last annual compliance report, and a review of the performance of disciplinary committees and panels;

(5) A description of any material compliance matters, including noncompliance issues identified through a compliance office review, look-back, internal or external audit finding, self-reported error, or validated complaint, and explains how they were resolved;

(6) Any objections to the annual compliance report by those persons who have oversight responsibility for the chief compliance officer; and

(7) A certification by the chief compliance officer that, to the best of his or her knowledge and reasonable belief, and under penalty of law, the annual compliance report is accurate and complete.

(f) *Submission of Annual Compliance Report by Chief Compliance Officer to the Commission.*

(1) Prior to submission of the annual compliance report to the Commission, the chief compliance officer shall provide the annual compliance report to the board of the registered swap execution facility for its review. If the swap execution facility does not have a board, then the annual compliance report shall be provided to the senior officer for their review. Members of the board and the senior officer may not require the chief compliance officer to make any changes to the report. Submission of the report to the board or the senior officer, and any subsequent discussion of the report, shall be recorded in board minutes or similar written record, as evidence of compliance with this requirement.

(2) The annual compliance report shall be provided electronically to the Commission not more than 60 days after the end of the registered swap execution facility's fiscal year.

(3) Promptly upon discovery of any material error or omission made in a previously filed compliance report, the chief compliance officer shall file an amendment with the Commission to

correct any material error or omission. An amendment shall contain the oath or certification required under paragraph (e)(7) of this section.

(4) A registered swap execution facility may request the Commission for an extension of time to file its compliance report based on substantial, undue hardship. Extensions for the filing deadline may be granted at the discretion of the Commission.

(5) Annual compliance reports filed pursuant to this section will be treated as exempt from mandatory public disclosure for purposes of the Freedom of Information Act and the Government in the Sunshine Act and parts 145 and 147 of this chapter, but will be available for official use by any official or employee of the United States and any State, by any self-regulatory organization of which the person filing the report is a member, and by any other person to whom the Commission believes disclosure is in the public interest.

(g) *Recordkeeping.* (1) The registered swap execution facility must maintain:

(i) A copy of the written policies and procedures, including the code of ethics and conflicts of interest policies adopted in furtherance of compliance with the Act and Commission regulations;

(ii) Copies of all materials created in furtherance of the chief compliance officer's duties listed in paragraphs (d)(6) and (d)(7) of this section, including records of any investigations or disciplinary actions taken by the swap execution facility;

(iii) Copies of all materials, including written reports provided to the board of directors or senior officer in connection with the review of the annual compliance report under paragraph (f)(1) of this section and the board minutes or similar written record of such review, that record the submission of the annual compliance report to the board of directors or senior officer; and

(iv) Any records relevant to the registered swap execution facility's annual compliance report, including, but not limited to, work papers and other documents that form the basis of the report, and memoranda, correspondence, other documents, and records that are (A) created, sent or received in connection with the annual compliance report and (B) contain conclusions, opinions, analyses, or financial data related to the annual compliance report.

(2) The registered swap execution facility shall maintain records in accordance with § 1.31 and part 45 of this chapter.

Appendix A to Part 37—Form SEF

COMMODITY FUTURES TRADING COMMISSION

FORM SEF

SWAP EXECUTION FACILITY

APPLICATION OR AMENDMENT TO APPLICATION FOR REGISTRATION

REGISTRATION INSTRUCTIONS

Intentional misstatements or omissions of material fact may constitute federal criminal violations (7 U.S.C. § 13 and 18 U.S.C. § 1001) or grounds for disqualification from registration.

DEFINITIONS

Unless the context requires otherwise, all terms used in the Form SEF have the same meaning as in the Commodity Exchange Act, as amended ("Act"), and in the General Rules and Regulations of the Commodity Futures Trading Commission ("Commission") thereunder.

GENERAL INSTRUCTIONS

1. Form SEF and Exhibits thereto are to be filed with the Commission by applicants for registration as a swap execution facility, or by a swap execution facility amending such registration, pursuant to Section 5h of the Act and the Commission's regulations thereunder. Applicants may prepare their own Form SEF but must follow the format prescribed herein. Upon the filing of an application for registration in accordance with the instructions provided herein, the Commission will publish notice of the filing and afford interested persons an opportunity to submit written data, views and arguments concerning such application. No application for registration shall be effective unless the Commission, by order, grants such registration.

2. For the purposes of this Form, the term "Applicant" shall include any applicant for registration as a swap execution facility or any registered swap execution facility that is seeking an amendment to its order of registration.

3. Individuals' names, except the executing signature in Item 11, shall be given in full (Last Name, First Name, Middle Name).

4. Signatures on all copies of the Form SEF filed with the Commission can be executed electronically. If the Form SEF is filed by a limited liability company, it must be signed in the name of the limited liability company by a member duly authorized to sign on the limited liability company's behalf; if filed by a partnership, it shall be signed in the name of the partnership by a general partner duly authorized; if filed by an unincorporated organization or association which is not a partnership, it shall be signed in the name of such organization or association by the managing agent—i.e., a duly authorized person who directs or manages or who participates in the directing or managing of its affairs; if filed by a corporation, it shall be signed in the name of the corporation by a principal officer duly authorized.

5. If Form SEF is being filed as an application for registration, all applicable items must be answered in full. If any item is not applicable, indicate by "none," "not applicable," or "N/A" as appropriate.

6. For the purposes of this Form SEF, the term "Applicant" shall include any applicant for registration as a swap execution facility or any swap execution facility that is amending Form SEF.

7. Under Section 5h of the Act and the Commission's regulations thereunder, the Commission is authorized to solicit the information required to be supplied by this Form SEF from any Applicant seeking registration as a swap execution facility and from any registered swap execution facility. Disclosure of the information specified on this Form SEF is mandatory prior to the start of the processing of an application for registration as a swap execution facility. The information provided with this Form SEF will be used for the principal purpose of determining whether the Commission should grant or deny registration to an Applicant. The Commission further may determine that other and additional information is required from the Applicant in order to process its application. Except in cases where confidential treatment is requested by the Applicant and granted by the Commission, pursuant to the Freedom of Information Act and the rules of the Commission thereunder, information supplied on this Form SEF will be included routinely in the public files of the Commission and will be available for inspection by any interested person. **A Form SEF which is not prepared and executed in compliance with applicable requirements and instructions may be returned as not acceptable for filing. Acceptance of this Form SEF, however, shall not constitute a finding that the Form SEF has been filed as required or that the information submitted is true, current or complete.**

UPDATING INFORMATION ON THE FORM SEF

1. Part 37 of the Commission's regulations requires that if any

information contained in this application, or any supplement or amendment thereto, is or becomes inaccurate for any reason, an amendment to Form SEF, or a submission under Part 40, in either case correcting such information must be filed promptly with the Commission.

2. Swap execution facilities filing Form SEF as an amendment need file only the facing page, the signature page (Item 10), and any pages on which an answer is being amended, together with any exhibits that are being amended. The submission of an amendment represents that the remaining items and exhibits remain true, current and complete as previously filed.

WHERE TO FILE

The Application Form SEF and appropriate exhibits must be filed electronically with the Secretary of the Commission in the form and manner as provided by the Commission.

COMMODITY FUTURES TRADING COMMISSION

FORM SEF

SWAP EXECUTION FACILITY

APPLICATION OR AMENDMENT TO APPLICATION FOR REGISTRATION

Exact name of Applicant as specified in charter

Address of principal executive offices

☐ If this is an **APPLICATION** for registration, complete in full and check here

☐ If this is an **AMENDMENT** to an application, or to an existing registration, list all items that are amended and check here

GENERAL INFORMATION

1. Name under which business of the swap execution facility will be conducted, if different than name specified on facing sheet:

2. If name of swap execution facility is hereby amended, state previous swap execution facility name:

3. Mailing address, if different than address specified on facing sheet:

Number and Street

City, State, Zip Code

3(a). Additional contact information:

Fax

Phone

Website

4. List of principal office(s) and address(es) where swap execution facility activities are/will be conducted:

Office
Address

BUSINESS ORGANIZATION

5. Applicant is a:
☐ Corporation
☐ Partnership
☐ Limited Liability Company
☐ Other form of organization (specify)

6. If Applicant is a corporation:
a. Date of incorporation:

b. State of incorporation:

7. If Applicant is a partnership:
a. Date of filing of partnership articles:

b. State in which filed:

8. If Applicant is a limited liability company:
a. Date of filing of Articles of Organization/Certificate of Formation:

b. State in which filed:

9. Applicant agrees and consents that the notice of any proceeding before the Commission in connection with its application for registration as a swap execution facility may be given by sending such notice by certified mail or confirmed telegram to the officer specified or person named below at the address given.

Name of person (if Applicant is a corporation, limited liability company or partnership, title of officer)

Name of Applicant

Number and Street

City State Zip Code

SIGNATURES

10. The Applicant has duly caused this application or amendment to be signed on its behalf by the undersigned, hereunto duly authorized, this ____ day of _____, 20____. The Applicant and the undersigned represent hereby that all information contained herein is true, current and complete. It is understood that all required items and Exhibits are considered integral parts of this Form SEF and that the submission of any amendment represents that all unamended items and Exhibits remain true, current, and complete as previously filed.

Name of Applicant

Manual signature of Member, General Partner, Managing Agent, or Principal Agent

Title

EXHIBITS INSTRUCTIONS

The following exhibits must be filed with the Commission by Applicants seeking registration as a swap execution facility, or by a registered swap execution facility amending its registration, pursuant to Section 5h of the Act and the Commission's regulations thereunder. The exhibits should be labeled according to the items specified in this Form SEF. If any exhibit is not applicable, please specify the exhibit letter and indicate by "none," "not applicable," or "N/A" as appropriate.

If the applicant is a newly formed enterprise and does not have the financial statements required pursuant to Items 9 and 10 (Exhibits I and J) of this form, the applicant should provide pro forma financial statements for the most recent six months or since inception, whichever is less.

EXHIBITS—BUSINESS ORGANIZATION

1. Attach as **Exhibit A**, the name of any person(s) who own(s) ten percent (10%) or more of the Applicant's stock or who, either directly or indirectly, through agreement or otherwise, in any other manner, may control or direct the management or policies of Applicant.

Provide as part of Exhibit A the full name and address of each such person and attach a copy of the agreement or, if there is none written, describe the agreement or basis upon which such person exercises or may exercise such control or direction.

2. Attach as **Exhibit B**, a list of the present officers, directors, governors (and, in the case of an Applicant that is not a corporation, the members of all standing committees grouped by committee), or persons performing functions similar to any of the foregoing, of the swap execution facility or of any entity that performs the regulatory activities of the Applicant, indicating for each:
a. Name
b. Title

c. Dates of commencement and termination of present term of office or position

d. Length of time each present officer, director, or governor has held the same office or position

e. Brief account of the business experience of each officer and director over the last five (5) years

f. Any other business affiliations in the derivatives and securities industry

g. For directors, list any committees on which they serve and any compensation received by virtue of their directorship

h. A description of:

(1) Any order of the Commission with respect to such person pursuant to Section 5e of the Act;

(2) Any conviction or injunction against such person within the past ten (10) years;

(3) Any disciplinary action with respect to such person within the last five (5) years;

(4) Any disqualification under Sections 8b and 8d of the Act;

(5) Any disciplinary action under Section 8c of the Act; and

(6) Any violation pursuant to Section 9 of the Act.

3. Attach as **Exhibit C**, a narrative that sets forth the fitness standards for the Board of Directors and its composition including the number or percentage of public directors.

4. Attach as **Exhibit D**, a narrative or graphic description of the organizational structure of the Applicant. Include a list of all affiliates of the Applicant and indicate the general nature of the affiliation. Note: If the swap execution facility activities of the Applicant are or will be conducted primarily by a division, subdivision, or other separate entity within the Applicant, corporation or organization, describe the relationship of such entity within the overall organizational structure and attach as Exhibit D a description only as it applies to the division, subdivision or separate entity, as applicable. Additionally, provide any relevant jurisdictional information, including any and all jurisdictions in which you or any affiliated entity are doing business, and registration status, including pending applications (e.g., country, regulator, registration category, date of registration). Provide the address for legal service of process for each jurisdiction, which cannot be a post office box.

5. Attach as **Exhibit E**, a description of the personnel qualifications for each category of professional employees employed by the Applicant or the division, subdivision, or other separate entity within the Applicant as described in item 4.

6. Attach as **Exhibit F**, an analysis of staffing requirements necessary to carry out operations of the Applicant as a swap execution facility and the name and qualifications of each key staff person.

7. Attach as **Exhibit G**, a copy of the constitution, articles of incorporation, formation or association with all amendments thereto, partnership or limited liability agreements, and existing by-laws, operating agreement, rules or instruments corresponding thereto, of the Applicant. Include any additional governance fitness information not included in Exhibit C. Provide a certificate of good standing dated within one week of the date of the Form SEF.

8. Attach as **Exhibit H**, a brief description of any material pending legal proceeding(s), other than ordinary and routine litigation incidental to the business, to which the Applicant or any of its affiliates is a party or to which any of its or their property is the subject. Include the name of the court or agency where the proceeding(s) are pending, the date(s) instituted, and the principal parties involved, a description of the factual basis alleged to underlie the proceeding(s), and the relief sought. Include similar information as to any proceeding(s) known to be contemplated by the governmental agencies.

EXHIBITS—FINANCIAL INFORMATION

9. Attach as **Exhibit I**:

a. (i) Balance sheet, (ii) Statement of income and expenses, (iii) Statement of cash flows, and (iv) Statement of sources and application of revenues and all notes or schedules thereto, as of the most recent fiscal year of the applicant, or of its parent company, if applicable. If a balance sheet and any statements certified by an independent public accountant are available, that balance sheet and statement should be submitted as Exhibit I.

b. Provide a narrative of how the value of the financial resources of the applicant is at least equal to a total amount that would enable the applicant to cover its operating costs for a period of at least one year, calculated on a rolling basis, and whether such financial resources include unencumbered, liquid financial assets (i.e. cash and/or highly liquid securities) equal to at least six months' operating costs.

c. Attach copies of any agreements establishing or amending a credit facility, insurance coverage, or other arrangement evidencing or otherwise supporting the applicant's conclusions regarding the liquidity of its financial assets.

d. Representations regarding sources and estimates for future ongoing operational resources.

10. Attach as **Exhibit J**, a balance sheet and an income and expense statement for each affiliate of the swap execution facility that also engages in swap execution facility activities as of the end of the most recent fiscal year of each such affiliate, and each affiliate of the swap execution facility that engages in designated contract market activities.

11. Attach as **Exhibit K**, the following:

a. A complete list of all dues, fees and other charges imposed, or to be imposed, by or on behalf of Applicant for its swap execution facility services that are provided on an exclusive basis and identify the service or services provided for each such due, fee, or other charge.

b. A description of the basis and methods used in determining the level and structure of the dues, fees and other charges listed in paragraph (a) of this item.

c. If the Applicant differentiates, or proposes to differentiate, among its customers, or classes of customers in the amount of any dues, fees, or other charges imposed for the same or similar exclusive services, so state and indicate the amount of each differential. In addition, identify and describe any differences in the cost of providing such services, and any other factors, that account for such differentiations.

EXHIBITS—COMPLIANCE

12. Attach as **Exhibit L**, a narrative and supporting documents that may be provided under other Exhibits herein, that describe the manner in which the Applicant is able to comply with each core principle. The Applicant should include an explanation, and any other forms of documentation the Applicant thinks will be helpful to its explanation, demonstrating how the swap execution facility will be able to comply with each core principle. To the extent that the application raises issues that are novel, or for which compliance with a core principle is not self-evident, include an explanation of how that item and the application satisfy the core principles.

13. Attach as **Exhibit M**, a copy of the Applicant's rules (as defined in § 40.1 of the Commission's regulations) and any technical manuals, other guides or instructions for users of, or participants in, the market, including minimum financial standards for members or market participants. Include rules citing applicable federal position limits and

aggregation standards in Part 151 of the Commission's regulations and any facility set position limit rules. Include rules on publication of daily trading information with regards to the requirements of Part 16 of the Commission's regulations. The Applicant should include an explanation, and any other forms of documentation the Applicant thinks will be helpful to its explanation, demonstrating how the swap execution facility will be able to comply with each core principle and how its rules, technical manuals, other guides or instructions for users of, or participants in, the market, or minimum financial standards for members or market participants provided in this Exhibit M help support the swap execution facility's compliance with the core principles.

14. Attach as **Exhibit N**, executed or executable copies of any agreements or contracts entered into or to be entered into by the Applicant, including third party regulatory service provider or member or user agreements that enable or empower the Applicant to comply with applicable core principles. Identify (1) the services that will be provided; and (2) the core principles addressed by such agreement.

15. Attach as **Exhibit O**, a copy of a compliance manual, and any other documents, that describe with specificity, the manner in which the Applicant will conduct trade practice, market and financial surveillance.

16. Attach as **Exhibit P**, a description of the Applicant's disciplinary and enforcement protocols, tools, and procedures and the arrangements for alternative dispute resolution.

17. Attach as **Exhibit Q**, as applicable, an explanation regarding:

a. For trading systems or platforms that enable market participants to engage in transactions through an order book:

(1) How the trading system or platform provides all orders and trades in an electronic form, and the timeliness in which the trading system or platform does so;

(2) How all market participants have the ability to immediately see and have the ability to transact on all bids and offers through the applicant's electronic automated trade-matching system or platform; and

(3) The trade matching algorithm and examples of how that algorithm works in various trading scenarios involving various types of orders.

b. For trading systems or platforms that enable market participants to engage in transactions on request for quote systems:

(1) How a market participant transmits a request for a quote to buy or sell a specific instrument to no less than five market participants in the trading system or platform, to which all such market participants may respond.

(2) How resting bids or offers may be taken into account.

c. For trading systems or platforms that enable market participants to engage in transactions via voice:

(1) How the terms of voice-based transactions are entered into the electronic trading system or platform.

d. How the timing delay described under § 37.9 is incorporated into the trading system or platform.

18. Attach as **Exhibit R**, a list of rules prohibiting specific trade practice violations.

19. Attach as **Exhibit S**, a discussion of how trading data will be maintained by the swap execution facility.

20. Attach as **Exhibit T**, a list of the name of the clearing organization(s) that will be clearing the Applicant's trades, and a representation that clearing members of that organization will be guaranteeing such trades.

21. Attach as **Exhibit U**, any information (described with particularity) included in the application that will be subject to a request for confidential treatment pursuant to § 145.9 of the Commission's regulations.

EXHIBITS—OPERATIONAL CAPABILITY

22. Attach as **Exhibit V**, information responsive to the Technology Questionnaire (link). The Technology Questionnaire focuses on information pertaining to the Applicant's program of risk analysis and oversight. Main topic areas include: information security; business continuity-disaster recovery planning and resources; capacity and performance planning; systems operations; systems development and quality assurance; and physical security and environmental controls.

Appendix B to Part 37—Guidance on, and Acceptable Practices in, Compliance With Core Principles

1. This appendix provides guidance on complying with core principles, both initially and on an ongoing basis, to maintain registration under Section 5h of the Act and this Part 37. Where provided, guidance is set forth in paragraph (a) following the relevant heading and can be used to demonstrate to the Commission compliance with the selected requirements of a core principle, under §§ 37.3 and 37.5 of this Part 37. The guidance for the core principle is illustrative only of the types of matters a swap execution facility may address, as applicable, and is not intended to be used as a mandatory checklist. Addressing the issues set forth in this appendix would help the Commission in its consideration of whether the swap execution facility is in compliance with the selected requirements of a core principle; provided however, that the guidance is not intended to diminish or replace, in any event, the obligations and requirements of applicants and swap execution facilities to comply with the regulations provided under this Part 37.

2. Where provided, acceptable practices meeting selected requirements of core principles are set forth in paragraph (b) following the guidance. Swap execution facilities that follow specific practices outlined in the acceptable practices for a core principle in this appendix will meet the selected requirements of the applicable core principle; provided however, that the acceptable practice is not intended to diminish or replace, in any event, the obligations and requirements of applicants and swap execution facilities to comply with the regulations provided under this Part 37. The acceptable practices are for illustrative purposes only and do not state the exclusive means for satisfying a core principle.

Core Principle 1 of Section 5h of the Act—Compliance With Core Principles

(A) *In general.* To be registered, and maintain registration, as a swap execution facility, the swap execution facility shall comply with—(i) all core principles described in Section 5h of the Act; and (ii) any requirement that the Commission may impose by rule or regulation pursuant to Section 8a(5) of the Act.

(B) *Reasonable Discretion of Swap Execution Facility.* Unless otherwise determined by the Commission by rule or regulation, a swap execution facility described in paragraph (a) shall have reasonable discretion in establishing the manner in which the swap execution facility complies with the core principles described in Section 5h of the Act.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 2 of Section 5h of the Act—Compliance With Rules

A swap execution facility shall:

(A) Establish and enforce compliance with any rule of the swap execution facility, including the terms and conditions of the swaps traded or processed on or through the swap execution facility and any limitation on access to the swap execution facility;

(B) Establish and enforce trading, trade processing, and participation rules that will deter abuses and have the capacity to detect, investigate, and enforce those rules, including means to provide market participants with impartial access to the market and to capture information that may be used in establishing whether rule violations have occurred;

(C) Establish rules governing the operation of the facility, including rules specifying trading procedures to be used in entering and executing orders traded or posted on the facility, including block trades; and

(D) Provide by its rules that, when a swap dealer or major swap participant enters into or facilitates a swap that is subject to the

mandatory clearing requirement of Section 2(h), the swap dealer or major swap participant shall be responsible for compliance with the mandatory trading requirement under Section 2(h)(8) of the Act.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 3 of Section 5h of the Act—Swaps Not Readily Susceptible to Manipulation

The swap execution facility shall permit trading only in swaps that are not readily susceptible to manipulation.

(a) *Guidance.*

(1) In general, a swap contract is an agreement to exchange a series of cash flows over a period of time based on some reference price, which could be a single price, such as an absolute level or a differential, or a price index calculated based on multiple observations. Moreover, such a reference price may be reported by the swap execution facility itself or by an independent third party. When listing a swap for trading, a swap execution facility must ensure a swap's compliance with Core Principle 3, paying special attention to the reference price used to determine the cash flow exchanges. Specifically, Core Principle 3 requires that the reference price used by a swap not be readily susceptible to manipulation. As a result, when identifying a reference price, a swap execution facility should either: (i) Calculate its own reference price using suitable and well-established acceptable methods or (ii) carefully select a reliable third-party index.

(2) The importance of the reference price's suitability for a given swap is similar to that of the final settlement price for a cash-settled futures. If the final settlement price is manipulated, then the swap contract does not serve its intended price discovery and risk management functions. Similarly, inappropriate reference prices cause the cash flows between the buyer and seller to differ from the proper amounts, thus benefitting one party and disadvantaging the other. Thus, careful consideration should be given to the potential for manipulation or distortion of the reference price.

(3) For swaps that are settled by physical delivery or by cash settlement refer to guidance in Appendix C to Part 38—Demonstration of Compliance that a contract is not readily susceptible to manipulation, Section b(2) and Section c(5), respectively.

(b) *Acceptable Practices.* [Reserved]

Core Principle 4 of Section 5h of the Act—Monitoring of Trading and Trade Processing

The swap execution facility shall:

(A) Establish and enforce rules or terms and conditions defining, or specifications detailing:

(1) Trading procedures to be used in entering and executing orders traded on or through the facilities of the swap execution facility; and

(2) Procedures for trade processing of swaps on or through the facilities of the swap execution facility; and

(B) Monitor trading in swaps to prevent manipulation, price distortion, and disruptions of the delivery or cash settlement process through surveillance, compliance, and disciplinary practices and procedures, including methods for conducting real-time monitoring of trading and comprehensive and accurate trade reconstructions.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 5 of Section 5h of the Act—Ability To Obtain Information

The swap execution facility shall:

(A) Establish and enforce rules that will allow the facility to obtain any necessary information to perform any of the functions described in this section;

(B) Provide the information to the Commission on request; and

(C) Have the capacity to carry out such international information-sharing agreements as the Commission may require.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 6 of Section 5h of the Act—Position Limits or Accountability

(A) *In general.* To reduce the potential threat of market manipulation or congestion, especially during trading in the delivery month, a swap execution facility that is a trading facility shall adopt for each of the contracts of the facility, as is necessary and appropriate, position limitations or position accountability for speculators.

(B) *Position limits.* For any contract that is subject to a position limitation established by the Commission pursuant to Section 4a(a) of the Act, the swap execution facility shall:

(1) Set its position limitation at a level no higher than the Commission limitation; and

(2) Monitor positions established on or through the swap execution facility for compliance with the limit set by the Commission and the limit, if any, set by the swap execution facility.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 7 of Section 5h of the Act—Financial Integrity of Transactions

The swap execution facility shall establish and enforce rules and procedures for ensuring the financial integrity of swaps entered on or through the facilities of the swap execution facility, including the clearance and settlement of the swaps pursuant to Section 2(h)(1) of the Act.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 8 of Section 5h of the Act—Emergency Authority

The swap execution facility shall adopt rules to provide for the exercise of emergency authority, in consultation or cooperation with the Commission, as is necessary and appropriate, including the authority to liquidate or transfer open positions in any swap or to suspend or curtail trading in a swap.

(a) *Guidance.* In consultation and cooperation with the Commission, a swap execution facility should have the authority to intervene as necessary to maintain markets with fair and orderly trading and to prevent or address manipulation or disruptive trading practices, whether the need for intervention arises exclusively from the swap execution facility's market or as part of a coordinated, cross-market intervention. Swap execution facility rules should include procedures and guidelines for decision making and implementation of emergency intervention that avoid conflicts of interest in accordance with the provisions of 17 CFR 40.11, and include alternate lines of communication and approval procedures to address emergencies associated with real time events. To address perceived market threats, the swap execution facility should have rules that allow it to take emergency actions, including imposing or modifying position limits, imposing or modifying price limits, imposing or modifying intraday market restrictions, imposing special margin requirements, ordering the liquidation or transfer of open positions in any contract, ordering the fixing of a settlement price, extending or shortening the expiration date or the trading hours, suspending or curtailing trading in any contract, transferring customer contracts and the margin, or altering any contract's settlement terms or conditions, or, if applicable, providing for the carrying out of such actions through its agreements with its third-party provider of clearing or regulatory services. In situations where a swap is traded on more than one platform, emergency action to liquidate or transfer open interest must be as directed, or agreed to, by the Commission or the Commission's staff. The swap execution facility should also have rules that allow it to take market actions as may be directed by the Commission. The Commission should be notified promptly of the swap execution facility's exercise of emergency action, explaining its decision-making process, the reasons for using its emergency authority, and how conflicts of interest were minimized, including the extent to which the swap execution facility considered the effect of its emergency action on the underlying markets and on markets that are linked or referenced to the contracts traded on its facility, including similar markets on other trading venues. Information on all regulatory actions carried out pursuant to a swap execution facility's emergency authority should be included in a timely submission of a certified rule pursuant to Part 40 of this Chapter.

(b) *Acceptable Practices.* [Reserved]

Core Principle 9 of Section 5h of the Act—Timely Publication of Trading Information

(A) *In general.* The swap execution facility shall make public timely information on price, trading volume, and other trading data on swaps to the extent prescribed by the Commission.

(B) *Capacity of swap execution facility.* The swap execution facility shall be required to have the capacity to electronically capture and transmit trade information with respect to transactions executed on the facility.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 10 of Section 5h of the Act—Recordkeeping and Reporting

(A) *In general.* A swap execution facility shall:

(1) Maintain records of all activities relating to the business of the facility,

including a complete audit trail, in a form and manner acceptable to the Commission for a period of 5 years;

(2) Report to the Commission, in a form and manner acceptable to the Commission, such information as the Commission determines to be necessary or appropriate for the Commission to perform the duties of the Commission under the Act; and

(3) Keep any such records relating to swaps defined in Section 1a(47)(A)(v) of the Act open to inspection and examination by the Securities and Exchange Commission.

(B) *Requirements.* The Commission shall adopt data collection and reporting requirements for swap execution facilities that are comparable to corresponding requirements for derivatives clearing organizations and swap data repositories.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 11 of Section 5h of the Act—Antitrust Considerations

Unless necessary or appropriate to achieve the purposes of this Act, the swap execution facility shall not:

(A) Adopt any rules or take any actions that result in any unreasonable restraint of trade; or

(B) Impose any material anticompetitive burden on trading or clearing.

(a) *Guidance.* An entity seeking registration as a swap execution facility may request that the Commission consider under the provisions of Section 15(b) of the Act, any of the entity's rules, including trading protocols or policies, and including both operational rules and the terms or conditions of products listed for trading, at the time of registration or thereafter. The Commission intends to apply Section 15(b) of the Act to its consideration of issues under this core principle in a manner consistent with that previously applied to contract markets.

(b) *Acceptable Practices.* [Reserved]

Core Principle 12 of Section 5h of the Act—Conflicts of Interest

The swap execution facility shall:

(A) Establish and enforce rules to minimize conflicts of interest in its decision-making process; and

(B) Establish a process for resolving the conflicts of interest.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 13 of Section 5h of the Act—Financial Resources

(A) *In general.* The swap execution facility shall have adequate financial, operational, and managerial resources to discharge each responsibility of the swap execution facility.

(B) *Determination of resource adequacy.* The financial resources of a swap execution facility shall be considered to be adequate if the value of the financial resources exceeds the total amount that would enable the swap execution facility to cover the operating costs of the swap execution facility for a one-year period, as calculated on a rolling basis.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 14 of Section 5h of the Act—System Safeguards

The swap execution facility shall:

(A) Establish and maintain a program of risk analysis and oversight to identify and minimize sources of operational risk, through the development of appropriate controls and procedures, and automated systems, that:

(1) Are reliable and secure; and

(2) Have adequate scalable capacity;

(B) Establish and maintain emergency procedures, backup facilities, and a plan for disaster recovery that allow for:

(1) The timely recovery and resumption of operations; and

(2) The fulfillment of the responsibilities and obligations of the swap execution facility; and

(C) Periodically conduct tests to verify that the backup resources of the swap execution facility are sufficient to ensure continued:

(1) Order processing and trade matching;

(2) Price reporting;

(3) Market surveillance; and

(4) Maintenance of a comprehensive and accurate audit trail.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Core Principle 15 of Section 5h of the Act—Designation of Chief Compliance Officer

(A) *In general.* Each swap execution facility shall designate an individual to serve as a chief compliance officer.

(B) *Duties.* The chief compliance officer shall:

(1) Report directly to the board or to the senior officer of the facility;

(2) Review compliance with the core principles in this subsection;

(3) In consultation with the board of the facility, a body performing a function similar to that of a board, or the senior officer of the facility, resolve any conflicts of interest that may arise;

(4) Be responsible for establishing and administering the policies and procedures required to be established pursuant to this section;

(5) Ensure compliance with the Act and the rules and regulations issued under the Act, including rules prescribed by the Commission pursuant to this section; and

(6) Establish procedures for the remediation of noncompliance issues found during compliance office reviews, look backs, internal or external audit findings, self-reported errors, or through validated complaints.

(C) *Requirements for procedures.* In establishing procedures under paragraph (b)(6), the chief compliance officer shall design the procedures to establish the handling, management response, remediation, retesting, and closing of noncompliance issues.

(D) *Annual reports.*

(1) *In general.* In accordance with rules prescribed by the Commission, the chief compliance officer shall annually prepare and sign a report that contains a description of:

(i) The compliance of the swap execution facility with the Act; and

(ii) The policies and procedures, including the code of ethics and conflict of interest policies, of the swap execution facility.

(2) *Requirements.* The chief compliance officer shall:

(i) Submit each report described in clause (1) with the appropriate financial report of the swap execution facility that is required to be submitted to the Commission pursuant to this section; and

(ii) Include in the report a certification that, under penalty of law, the report is accurate and complete.

(a) *Guidance.* [Reserved]

(b) *Acceptable Practices.* [Reserved]

Dated: December 16, 2010.

By the Commission.

David A. Stawick,

Secretary.

Appendices to Core Principles and Other Requirements for Swap Execution Facilities—Commission Voting Summary and Statements of Commissioners

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Dunn, Chilton and O'Malia voted in the affirmative; Commissioner Sommers voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler

I support the proposed rulemaking to fulfill Congress's mandate to have rules and core principles requirements for swap execution facilities (SEFs). The proposed rule also fulfills Congress's mandate to promote transparency through the trading of swaps on SEFS.

The proposed rule will provide for all market participants an ability to execute or trade with other market participants. It will afford market participants with the ability to make firm bids or offers to all other market participants. It also will allow them to make indications of interest—or what is often referred to as "indicative quotes"—to other participants. Furthermore, it will allow participants to request quotes from other market participants. These methods will provide hedgers, investors and Main Street businesses both the flexibility to execute and trade by a number of methods, but also the benefits of transparency and more market competition. I believe that transparency and competition in markets is consistent with Congress mandated in the definition of a swap execution facility, whereby all market participants can communicate with all market participants such that everybody gets the benefit of a competitive and transparent price discovery process.

The proposal does allow participants, though, to do request for quotes, whereby they would reach out to a minimum number of other market participants for quotes. It also allows that, for block transactions, swap transactions involving non-financial end-users, swaps that are not "made available for trading" and bilateral transactions, market

participants can get the benefits of the swap execution facilities' greater transparency or, if they wish, would still be allowed to execute by voice or other means of trading.

To fulfill Congress's mandate that, the rule requires SEFs to provide impartial access to market participants for trading on the platform or system.

The proposed rule also would require SEFs to—on a yearly basis—state which contracts are deemed "available for trading," based on factors including trading activity and open interest. The rule, if finalized, goes into effect in January 2012. This will give the markets time to adapt, allow SEFs to tell the market what contracts are available for trading.

Appendix 3—Statement of Commissioner Sommers

I disagree with several aspects of the Swap Execution Facility (SEF) proposal the Commission is issuing today and seek public comment on alternative language for Section 37.9, *Permitted Execution Methods.*

Dodd-Frank defines a SEF as a "trading system or platform in which multiple participants have the ability to execute or trade swaps by accepting bids and offers made by multiple participants in the facility or system, through any means of interstate commerce, including any trading facility." As I have pointed out in my public speaking engagements over the past few months, the term "trading facility" is defined in the Commodity Exchange Act (Act), but the terms "trading system" and "platform" are not. By introducing these new, undefined terms into the Act, and by specifying that SEFs should facilitate the trading of swaps through any means of interstate commerce, I believe Congress intended a broad model for executing swaps on SEFs, both cleared, uncleared, liquid or bespoke. The goals identified by Dodd-Frank for registering SEFs are "to promote the trading of swaps on swap execution facilities and to promote pre-trade price transparency in the swaps market." In my view, the best way to achieve these twin goals is to adopt a model that provides the maximum amount of flexibility as to the method of trading. Unfortunately, this proposal does not do that.

Section 37.9, which governs the types of execution methods that SEFs may offer, is a key provision of this proposed regulation. While it permits alternative methods of execution, such as the trading facility model and the request for quote model, it also requires that to be registered as a SEF an applicant must, at a minimum, provide market participants "with the ability to post both firm and indicative quotes on a centralized electronic screen accessible to all market participants who have access to the swap execution facility." In my view this provision is not mandated by Dodd-Frank and may limit competition by shutting out applicants who wish to offer request for quote services without this functionality. I believe this interpretation of the statute, and other requirements within this section, are far too restrictive.

As a result of my concerns, we worked throughout the past week to include alternative language for Section 37.9 in the proposal. I believe this alternative language complies with Dodd-Frank and would promote both pre-trade price transparency and the trading of swaps on SEFs. Including the alternative would have given the public an opportunity to comment, in accordance with the Administrative Procedure Act, on both the alternative language and the language contained in the proposed rule. I am deeply disappointed that despite a commitment to a transparent process in promulgating the Dodd-Frank rules, the alternative language is not in the proposal today and we are not giving the public the opportunity to comment on it. That alternative language is set forth below.

§ 37.9 Permitted Execution Methods.

(a) *Definitions.*

(1) As used in this Part 37:

(i) *Order Book System* means:

(A) An electronic trading facility, as that term is defined in section 1a(16) of the Act;

(B) A trading facility, as that term is defined in section 1a(51) of the Act;

(C) A trading system or platform in which all market participants in the trading system or platform can enter multiple bids and offers, observe bids and offers entered by other market participants, and choose to transact on such bids and offers; or

(D) Any such other trading system or platform as may be determined by the Commission.

(ii) *Request for Quote System* means:

(A) A trading system or platform in which a market participant transmits a request for a quote to buy or sell a specific instrument to all other market participants in the trading system or platform to which all market participants may respond;

(B) A trading system or platform in which a market participant transmits a request for a quote to buy or sell a specific instrument to more than one potential counterparty. Upon receipt of responsive quotes from any of the potential counterparties, the original requester may accept a responsive quote and complete a transaction with any one of the responsive counterparties;

(C) A trading system or platform in which multiple market participants can both (i) view real-time electronic streaming quotes, both firm or indicative, from multiple potential counterparties on a centralized screen; and (ii) have the option to complete a transaction by (A) accepting a firm streaming quote, or (B) transmitting a request for a quote to more than one market participant, based upon an indicative streaming quote, taking into account any resting bids or offers that have been communicated to the requester along with any responsive quotes; or

(D) Any such other trading system or platform as may be determined by the Commission.

(iii) *Voice-Based System* means:

(A) A trading system or platform in which a market participant executes or trades a swap using a telephonic line or other voice-based service.

(2) Swaps subject the clearing requirements under the Act that are made available for trading pursuant to § 37.10 may be executed or traded on an Order Book System, a Request for Quote System, or any such other trading system or platform as may be determined by the Commission.

(3) Swaps not subject to the clearing requirements under the Act may be executed or traded on an Order Book System, a Request for Quote System, a Voice-Based System, or any such other trading system or platform as may be determined by the Commission.

(4) A swap execution facility can be an Order Book System, a Request for Quote System, or any such other trading system or platform as may be determined by the Commission, or any combination of the aforementioned systems.

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Part III

Department of Health and Human Services

45 CFR Part 170

Establishment of the Permanent Certification for Health Information Technology; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991–AB59

Establishment of the Permanent Certification Program for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule establishes a permanent certification program for the purpose of certifying health information technology (HIT). This final rule is issued pursuant to the authority granted to the National Coordinator for Health Information Technology (the National Coordinator) by section 3001(c)(5) of the Public Health Service Act (PHSA), as added by the Health Information Technology for Economic and Clinical Health (HITECH) Act. The permanent certification program will eventually replace the temporary certification program that was previously established by a final rule. The National Coordinator will use the permanent certification program to authorize organizations to certify electronic health record (EHR) technology, such as Complete EHRs and/or EHR Modules. The permanent certification program could also be expanded to include the certification of other types of HIT.

DATES: These regulations are effective February 7, 2011. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of February 7, 2011.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

Acronyms

APA Administrative Procedure Act
ARRA American Recovery and Reinvestment Act of 2009
CAH Critical Access Hospital
CCHIT Certification Commission for Health Information Technology
CGD Certification Guidance Document
CHPL Certified Health Information Technology Products List
CMS Centers for Medicare & Medicaid Services
CORE Committee on Operating Rules for Information Exchange®
CAQH Council for Affordable Quality Healthcare
EHR Electronic Health Record
FACA Federal Advisory Committee Act
FFP Federal Financial Participation
FFS Fee for Service (Medicare Program)
HHS Department of Health and Human Services
HIPAA Health Insurance Portability and Accountability Act of 1996
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
ILAC International Laboratory Accreditation Cooperation
ISO International Organization for Standardization
IT Information Technology
LAP Laboratory Accreditation Program
MA Medicare Advantage
MRA Mutual/Multilateral Recognition Arrangement
NIST National Institute of Standards and Technology
NPRM Notice of Proposed Rulemaking
NVCASE National Voluntary Conformity Assessment System Evaluation
NVLAP National Voluntary Laboratory Accreditation Program
OIG Office of Inspector General
OMB Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
ONC–AA ONC–Approved Accreditor
ONC–ACB ONC–Authorized Certification Body
ONC–ATCB ONC–Authorized Testing and Certification Body
OPM Office of Personnel Management
PHSA Public Health Service Act
RFA Regulatory Flexibility Act
RIA Regulatory Impact Analysis
SDO Standards Development Organization
SSA Social Security Act

Table of Contents

I. Background

A. Previously Defined Terminology

In addition to the new terms and definitions created by this rule, the following terms have the same meaning as provided at 45 CFR 170.102.

- *Certification criteria*
- *Certified EHR Technology*
- *Complete EHR*
- *Day or days*
- *Disclosure*
- *EHR Module*
- *Implementation specification*
- *Qualified EHR*
- *Standard*

The definition of the term ONC-Authorized Testing and Certification Body (ONC–ATCB) can be found at 45 CFR 170.402.

B. Legislative and Regulatory History

1. Legislative History

The HITECH Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the PHSA and created "Title XXX—Health Information Technology and Quality" (Title XXX) to improve health care quality, safety, and efficiency through the promotion of HIT and electronic health information exchange. Section 3001 of the PHSA establishes the Office of the National Coordinator for Health Information Technology (ONC). Title XXX of the PHSA provides the National Coordinator for Health Information Technology (the National Coordinator) and the Secretary of Health and Human Services (the Secretary) with new responsibilities and authorities related to HIT. The HITECH Act also amended several sections of the Social Security Act (SSA) and in doing so established the availability of incentive payments to eligible professionals and eligible hospitals to promote the adoption and meaningful use of Certified EHR Technology. References to "eligible hospitals" in this final rule shall mean "eligible hospitals and/or critical access hospitals" unless otherwise indicated.

a. Standards, Implementation Specifications, and Certification Criteria

With the passage of the HITECH Act, two new Federal advisory committees were established, the HIT Policy Committee and the HIT Standards Committee (sections 3002 and 3003 of the PHSA, respectively). Each is responsible for advising the National Coordinator on different aspects of standards, implementation specifications, and certification criteria. The HIT Policy Committee is responsible for, among other duties, recommending priorities for the development, harmonization, and recognition of standards, implementation specifications, and certification criteria, while the HIT Standards Committee is responsible for recommending standards, implementation specifications, and certification criteria for adoption by the Secretary under section 3004 of the PHSA consistent with the ONC-coordinated Federal Health IT Strategic Plan.

Section 3004 of the PHSA defines how the Secretary adopts standards, implementation specifications, and certification criteria. Section 3004(a) of the PHSA defines a process whereby an obligation is imposed on the Secretary to review standards, implementation specifications, and certification criteria and identifies the procedures for the Secretary to follow to determine whether to adopt any group of standards, implementation specifications, or certification criteria included among National Coordinator-endorsed recommendations.

b. Medicare and Medicaid EHR Incentive Programs

Title IV, Division B of the HITECH Act establishes incentive payments under the Medicare and Medicaid programs for eligible professionals and eligible hospitals that meaningfully use Certified EHR Technology. The Centers for Medicare & Medicaid Services (CMS) is charged with developing the Medicare and Medicaid EHR Incentive Programs.

i. Medicare EHR Incentive Program

Section 4101 of the HITECH Act added new subsections to section 1848 of the SSA to establish incentive payments for the meaningful use of Certified EHR Technology by eligible professionals participating in the Medicare Fee-for-Service (FFS) program beginning in calendar year (CY) 2011, and beginning in CY 2015, downward payment adjustments for covered professional services provided by eligible professionals who are not meaningful users of Certified EHR Technology. Eligible professionals for the Medicare EHR incentive program are physicians as defined in section 1861(r) of the SSA. A hospital-based eligible professional furnishes substantially all of his or her Medicare-covered professional services in a hospital inpatient or emergency room setting. Hospital-based eligible professionals are not eligible for the Medicare incentive payments. Section 4101(c) of the HITECH Act added a new subsection to section 1853 of the SSA that provides incentive payments to Medicare Advantage (MA) organizations for their affiliated eligible professionals who meaningfully use Certified EHR Technology beginning in CY 2011 and beginning in CY 2015, downward payment adjustments to MA organizations to account for certain affiliated eligible professionals who are not meaningful users of Certified EHR Technology.

Section 4102 of the HITECH Act added new subsections to section 1886 of the SSA that establish incentive payments for the meaningful use of Certified EHR Technology by subsection (d) hospitals (defined under section 1886(d)(1)(B) of the SSA) that participate in the Medicare FFS program

beginning in Federal fiscal year (FY) 2011 and beginning in FY 2015, downward payment adjustments to the market basket updates for inpatient hospital services provided by such hospitals that are not meaningful users of Certified EHR Technology. Section 4102(b) of the HITECH Act amends section 1814 of the SSA to provide critical access hospitals that meaningfully use Certified EHR Technology with an incentive payment based on the hospitals' reasonable costs beginning in FY 2011 and downward payment adjustments for inpatient hospital services provided by such hospitals that are not meaningful users of Certified EHR Technology for cost reporting periods beginning in FY 2015. Section 4102(c) of the HITECH Act adds a new subsection to section 1853 of the SSA to provide incentive payments to MA organizations for certain affiliated eligible hospitals that meaningfully use Certified EHR Technology and beginning in FY 2015, downward payment adjustments to MA organizations for those affiliated hospitals that are not meaningful users of Certified EHR Technology.

ii. Medicaid EHR Incentive Program

Section 4201 of the HITECH Act amends section 1903 of the SSA to provide 100 percent Federal financial participation (FFP) for States' expenditures for incentive payments to eligible health care providers participating in the Medicaid program to adopt, implement, or upgrade and meaningfully use Certified EHR Technology and 90 percent FFP for States' reasonable administrative expenses related to the administration of the incentive payments. For the Medicaid EHR incentive program, eligible professionals are physicians (primarily doctors of medicine and doctors of osteopathy), dentists, nurse practitioners, certified nurse midwives, and physician assistants practicing in a Federally Qualified Health Center led by a physician assistant or Rural Health Clinic that is so led. Eligible hospitals that can participate in the Medicaid EHR incentive program are acute care hospitals (including cancer and critical access hospitals) and children's hospitals.

c. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the "National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle" (*i.e.,* certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also "include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act."

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HIT Standards Committee, "shall support the establishment of a conformance testing infrastructure, including the development of technical test beds." The United States Congress also indicated that "[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing."

2. Regulatory History and Related Guidance

a. Initial Set of Standards, Implementation Specifications, and Certification Criteria Interim and Final Rules

In accordance with section 3004(b)(1) of the PHSA, the Secretary issued an interim final rule with request for comments entitled "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" (75 FR 2014, Jan. 13, 2010) (the "HIT Standards and Certification Criteria interim final rule"), which adopted an initial set of standards, implementation specifications, and certification criteria. After consideration of the public comments received on the interim final rule, a final rule was issued to complete the adoption of the initial set of standards, implementation specifications, and certification criteria and realign them with the final objectives and measures established for meaningful use Stage 1. Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule, 75 FR 44590 (July 28, 2010) (the "HIT Standards and Certification Criteria final rule"). On October 13, 2010, an interim final rule was issued to remove certain implementation specifications related to public health surveillance that had been previously adopted in the HIT Standards and Certification Criteria final rule (75 FR 62686).

The standards, implementation specifications, and certification criteria adopted by the Secretary establish the capabilities that Certified EHR Technology must include in order to, at a minimum, support the achievement of meaningful use Stage 1 by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs final rule (*see* 75 FR 44314 for more information about meaningful use and the Stage 1 requirements).

b. Medicare and Medicaid EHR Incentive Programs Proposed and Final Rules

On January 13, 2010, CMS published in the **Federal Register** (75 FR 1844) the Medicare and Medicaid EHR Incentive Programs proposed rule. The rule proposed a definition for Stage 1 meaningful use of Certified EHR Technology and regulations associated with the incentive payments made available under Division B, Title IV of the HITECH Act.

Subsequently, CMS published a final rule for the Medicare and Medicaid EHR Incentive Programs in the **Federal Register** (75 FR 44314) on July 28, 2010 (the "Medicare and Medicaid EHR Incentive Programs final rule"), simultaneously with the publication of the HIT Standards and Certification Criteria final rule. The final rule published by CMS established the objectives and associated measures that eligible professionals and eligible hospitals must satisfy in order to demonstrate "meaningful use" during Stage 1.

c. HIT Certification Programs Proposed Rule and the Temporary and Permanent Certification Programs Final Rules

Section 3001(c)(5) of the PHSA specifies that the National Coordinator "shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted [by the Secretary] under this subtitle." Based on this authority, we proposed both a temporary and permanent certification program for HIT in a notice of proposed rulemaking entitled "Proposed Establishment of Certification Programs for Health Information Technology" (75 FR 11328, Mar. 10, 2010) (the "Proposed Rule"). In the Proposed Rule, we proposed to use the certification programs for the purposes of testing and

certifying HIT. We also specified the processes the National Coordinator would follow to authorize organizations to perform the certification of HIT. We stated in the Proposed Rule that we expected to issue separate final rules for each of the certification programs. Consistent with our proposal, we issued a final rule to establish a temporary certification program, which was published in the **Federal Register** (75 FR 36158) on June 24, 2010 (the "Temporary Certification Program final rule"). To conclude our proposed approach, we are issuing this final rule to establish a permanent certification program whereby the National Coordinator will authorize organizations to certify Complete EHRs, EHR Modules, and/or other types of HIT. As provided in the Temporary Certification Program final rule, the temporary certification program will sunset on December 31, 2011, or on a subsequent date if the permanent certification program is not fully constituted at that time.

d. Recognized Certification Bodies as Related to the Physician Self-Referral Prohibition and Anti-Kickback EHR Exception and Safe Harbor Final Rules

In August 2006, the Department of Health and Human Services (HHS) published two final rules in which CMS and the Office of Inspector General (OIG) promulgated an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute, respectively, for certain arrangements involving the donation of interoperable EHR software to physicians and other health care practitioners or entities (71 FR 45140 and 71 FR 45110, respectively). The exception and safe harbor provide that EHR software will be "deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the [physician/recipient]." ONC published separately a Certification Guidance Document (CGD) (71 FR 44296) to explain the factors ONC would use to determine whether to recommend to the Secretary an organization for "recognized certification body" status. The CGD served as a guide for ONC to evaluate applications for "recognized certification body" status and provided the information an organization would need to apply for and obtain such status. Under the process specified in the CGD, the Certification Commission for Health Information Technology (CCHIT) was the only organization that both applied for and had been granted "recognized certification body" status.

In section VI of the CGD, ONC notified the public, including potential applicants, that the recognition process explained in the CGD would be formalized through notice and comment rulemaking and that when a final rule has been promulgated to govern the process by which a "recognized certification body" is determined, certification bodies recognized under the CGD would be required to complete new applications and successfully demonstrate compliance with all requirements of the final rule.

In the Proposed Rule, we began the formal notice and comment rulemaking described in the CGD. We stated that the processes we proposed for the temporary certification program and permanent certification program, once finalized, would supersede the CGD, and the authorization process would constitute the new established method for "recognizing" certification bodies, as referenced in the physician self-referral prohibition and anti-kickback EHR exception and safe harbor final rules. As a result of our proposal, certifications issued by a certification body "authorized" by the National Coordinator would constitute certification by "a certifying body recognized by the Secretary" in the context of the physician self-referral EHR exception and anti-kickback EHR safe harbor. After consideration of the public comments we received on this proposal, we determined that the ONC–ATCB and ONC–ACB "authorization" processes would constitute the Secretary's "recognition" of a certification body and finalized our proposal for both the temporary certification program and permanent certification program in the Temporary Certification Program final rule (75 FR 36186). Any questions regarding compliance with the exception or safe harbor should be directed to CMS and OIG, respectively.

II. Overview of the Permanent Certification Program

The permanent certification program provides a process by which an organization or organizations may become an ONC–Authorized Certification Body (ONC–ACB) authorized by the National Coordinator to perform the certification of Complete EHRs and/or EHR Modules. ONC–ACBs may also be authorized under the permanent certification program to perform the certification of other types of HIT in the event that applicable certification criteria are adopted by the Secretary. We note, however, that the certification of Complete EHRs, EHR Modules, or potentially other types of HIT under the permanent certification program would not constitute a replacement or substitution for other Federal requirements that may be applicable.

Under the permanent certification program, the National Coordinator will accept applications for ONC–ACB status after the effective date of this final rule and at any time during the existence of the permanent certification program. In order to become an ONC–ACB, an organization or organizations must submit an application to the National Coordinator to demonstrate its competency and ability to certify Complete EHRs, EHR Modules, and/or potentially other types of HIT by documenting its accreditation by the ONC–Approved Accreditor (ONC–AA) and by meeting other specified application requirements. These organizations will be required to remain in good standing by adhering to the Principles of Proper Conduct for ONC–ACBs. ONC–ACBs will also be required to follow the conditions and requirements applicable to the certification of Complete EHRs, EHR Modules, and/or potentially other types of HIT as specified in this final rule. The permanent certification program will eventually replace the temporary certification program that was established previously by a final rule (75 FR 36158). Testing and certification under the permanent certification program is expected to begin on January 1, 2012, or upon a subsequent date when the National Coordinator determines that the permanent certification program is fully constituted. The permanent certification program has no anticipated sunset date. ONC–ACBs are required to renew their status every three years under the permanent certification program.

III. Provisions of the Permanent Certification Program; Analysis of and Response to Public Comments on the Proposed Rule

A. Overview

This section discusses and responds to the comments that were timely received on the proposed provisions of the permanent certification program that were set forth in the Proposed Rule. As explained in the Proposed Rule, we chose to propose both the temporary certification program and the permanent certification program in the same notice of proposed rulemaking in order to offer the public a broader context for each of the programs and an opportunity to make more informed comments on our proposals. We noted that we expected to receive public comments that were

applicable to both of the proposed certification programs due to the fact that we had proposed certain elements that were the same or similar for both programs. As anticipated, we received comments in response to the Proposed Rule that were applicable to both certification programs. In the Temporary Certification Program final rule, we discussed and responded to all of the comments that were applicable to the temporary certification program. Because some of those comments are also related to provisions of the permanent certification program, we discuss them again in this final rule and respond to them in the context of the permanent certification program. Many of the common elements that we proposed for both the temporary and the permanent certification programs are based on the same or similar underlying policy reasons or objectives. As a result, we often reach the same or similar conclusions in this final rule as we did in the Temporary Certification Program final rule. In responding to comments in this final rule, we often make reference to or restate parts of our responses to comments that we provided in the Temporary Certification Program final rule due to the various similarities that exist between the temporary and permanent certification programs.

We have structured this section of the final rule based on the proposed regulatory sections of the permanent certification program and discuss each regulatory section sequentially. For each discussion of a regulatory provision, we first restate or paraphrase the provision as proposed in the Proposed Rule as well as identify any correlated issues for which we sought public comment. Second, we summarize the comments received. Lastly, we provide our response to the comments and indicate whether we are finalizing the provision as proposed in the Proposed Rule or modifying the proposed provision in response to public comment, to provide clarification, or to correct inadvertent errors. Comments on dual-accredited testing and certification bodies, the concept of "self-developed," validity and expiration of certifications, differential or "gap" certification, barriers to entry for potential ONC–ACBs, an ONC-managed certification program, general comments, and comments beyond the scope of this final rule are discussed towards the end of the preamble.

B. Scope and Applicability

In the Proposed Rule, we indicated in § 170.500 that the permanent certification program would serve to implement section 3001(c)(5) of the PHSA, and that subpart E would also set forth the rules and procedures related to the permanent certification program for HIT administered by the National Coordinator. Under § 170.501, we proposed that subpart E would establish the processes that applicants for ONC–ACB status must follow to be granted ONC–ACB status by the National Coordinator, the processes the National Coordinator would follow when assessing applicants and granting ONC–ACB status, and the requirements of ONC–ACBs for certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of part 170. We also proposed that subpart E would establish the processes that accreditation organizations would follow to request approval from the National Coordinator, the processes the National Coordinator would follow to approve an accreditation organization under the permanent certification program, and the ongoing responsibilities of an ONC–AA.

Comments. We received comments that expressed general support for the permanent certification program. We also received a few comments regarding the extension of the scope of the permanent certification program to other types of HIT. One commenter asserted that there was a need for the permanent certification program to focus on the implementation of the nationwide health information network.

Response. We appreciate the comments expressing support for the permanent certification program. We intend to address the governance mechanisms for the nationwide health information network through a separate rulemaking. We will more specifically address the comments related to other types of HIT when we discuss proposed § 170.553 later in this preamble, but we note here that we are revising § 170.501 to acknowledge the possibility for ONC–ACBs to certify "other types of HIT" under the permanent certification program. We are also revising § 170.501 to clearly state that this subpart includes requirements that ONC–ACBs must follow to maintain their status as ONC–ACBs under the permanent certification program. These references were inadvertently left out of § 170.501 in the Proposed Rule although they were included elsewhere in the preamble discussion and regulation text.

C. Definitions

In the Proposed Rule, we proposed to define four terms related to the permanent certification program.

1. Day or Days

We proposed to add the definition of "day or days" to § 170.102. We proposed to define "day or days" to mean a calendar day or calendar days. We added this definition to § 170.102 in the Temporary Certification Program final rule. Further, we did not receive any comments on this definition related to the permanent certification program. Therefore, references to "day" or "days" in provisions of subpart E have the meaning provided to them in § 170.102.

2. Applicant

We proposed in § 170.502 to define "applicant" to mean a single organization or a consortium of organizations that seek to become an ONC–ACB by requesting and subsequently submitting an application for ONC–ACB status to the National Coordinator. We did not receive any comments on this proposed definition. We are, however, revising the definition of "applicant" by removing the condition that an "applicant" must "request" an application. We clearly indicated in the Proposed Rule preamble that, unlike under the temporary certification program, "applicants" for ONC–ACB status would no longer need to request an application.

3. ONC–ACB

We proposed in § 170.502 to define an "ONC–Authorized Certification Body" or "ONC–ACB" to mean an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to subpart E to perform the certification of, at minimum, Complete EHRs and/or EHR Modules using the applicable certification criteria adopted by the Secretary.

Comments. A commenter noted that the proposed definition would not preclude an ONC–ACB from certifying other types of HIT, but would require an ONC–ACB to be able to certify Complete EHRs and/or EHR Modules. The commenter contended that this requirement will prevent organizations that may want to certify only other types of HIT (and not Complete EHRs or EHR Modules) from becoming ONC–ACBs.

Response. We did not intend to preclude an organization from seeking authorization to certify only other types of HIT besides Complete EHRs and EHR Modules, when and if the option becomes available. To the contrary, as noted in proposed § 170.510, we indicated that an applicant could seek authorization to certify Complete EHRs, EHR Modules, other types of HIT, or any

combination of the three. However, as we specified in the Proposed Rule preamble and in proposed § 170.510, the Secretary must first adopt applicable certification criteria under subpart C of part 170 before authorization to certify other types of HIT could be granted to ONC–ACBs.

In response to the comment and to be consistent with our intent as expressed in § 170.510, we are removing "at a minimum" from the definition of ONC–ACB. This will allow an organization or consortium of organizations to become an ONC–ACB that is authorized to certify only other types of HIT besides Complete EHRs and/or EHR Modules. We are also revising the definition by replacing "using the applicable certification criteria adopted by the Secretary" with "under the permanent certification program." We believe this revision more clearly reflects the focus of an ONC–ACB and is more consistent with the definition of an ONC–ATCB that we finalized in the Temporary Certification Program final rule. We note that ONC–ACBs that are authorized to certify Complete EHRs and/or EHR Modules will be required to perform certifications using the applicable certification criteria adopted by the Secretary based on the provisions of §§ 170.545 and 170.550.

4. ONC–AA

We proposed in § 170.502 to define the term "ONC–Approved Accreditor" or "ONC–AA" to mean an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

We did not receive any comments on this proposed definition. Therefore, we are finalizing this definition without modification.

D. ONC–AA Status, On-going Responsibilities and Reconsideration of Request for ONC–AA Status

In the Proposed Rule, we proposed processes for requesting ONC–AA status, the process for reviewing and approving an ONC–AA, the ongoing responsibilities of an ONC–AA, and the process for an accreditation organization to request reconsideration of its denied request for ONC–AA status.

1. ONC–AA Status

We proposed in § 170.503 that the National Coordinator would approve only one ONC–AA at a time. We proposed that in order for an accreditation organization to become an ONC–AA, it would need to submit a request in writing to the National Coordinator along with certain information to demonstrate its ability to serve as an ONC–AA. This information included: A detailed description of how the accreditation organization conforms to ISO/IEC17011:2004 (ISO 17011) and its experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (Guide 65); a detailed description of the accreditation organization's accreditation requirements and how the requirements complement the Principles of Proper Conduct for ONC–ACBs; detailed information about the accreditation organization's procedures that would be used to monitor ONC–ACBs; detailed information, including education and experience, about the key personnel who would review organizations for accreditation; and the accreditation organization's procedures for responding to, and investigating, complaints against ONC–ACBs.

We proposed that the National Coordinator would be permitted up to 30 days to review a request for ONC–AA status from an accreditation organization upon receipt and issue a determination on whether the organization is approved. We proposed that the National Coordinator's determination would be based on the information and the completeness of the descriptions provided, as well as each accreditation organization's overall accreditation experience. We proposed that the National Coordinator would review requests by accreditation organizations for ONC–AA status in the order they were received and would approve the first qualified accreditation organization based on the information required to be submitted with a request for ONC–AA status. We proposed that an ONC–AA's status would expire not later than 3 years from the date its status was granted by the National Coordinator. We further proposed that beginning 120 days prior to the expiration of the then-current ONC–AA's status, the National Coordinator would again accept requests for ONC–AA status.

We specifically requested comment on whether it would be in the best interest of the ONC–ACB applicants and Complete EHR and EHR Module developers to allow for more than one ONC–AA at a time and whether we should extend the duration of an ONC–AA's term to 5 years, shorten it to 2 years, or identify a different period of time.

Comments. Commenters expressed support for an independent accreditation body, which they stated would provide an open and transparent process. One commenter, however, asked for clarification as to why we proposed to have an accreditor independent of ONC. The commenter stated that the proposal seemed to introduce unnecessary overhead. A commenter also requested clarification of the requirement for an ONC–AA to conform to ISO 17011. Another commenter recommended that we require an ONC–AA to be recognized under the NIST National Voluntary Conformity Assessment Systems Evaluation, or "NVCASE" program. The commenter further recommended that the ONC–AA should demonstrate its ISO 17011 compliance for the ISO Guide 65 scope by being a signatory to the International Accreditation Forum's Mutual/Multilateral Recognition Agreement (MRA) for product certification, which is verified by regular peer assessments. The commenter stated that such a requirement would mirror a benchmark set elsewhere for similar Federal agency program requirements for an accreditation body (*i.e.,* the U.S. EPA "WaterSense" program requirements).

Many commenters recommended that there be only one ONC–AA to ensure consistency, while only two commenters expressed openness to having more than one ONC–AA at a time. One of the commenters favoring more than one ONC–AA opined that the approval of more than one accreditor would ensure that all potential ONC–ACBs could be timely accredited and that the unique needs of potential ONC–ACBs would be adequately addressed, such as in the case of organizations that seek to certify other types of HIT besides Complete EHRs and EHR Modules. The other commenter suggested that we consider approving more than one ONC–AA if we anticipate a high volume of applicants for ONC–ACB status. One commenter stated that, given the importance of the ONC–AA in ensuring that the accredited certification bodies operate in a fair and effective manner, the ONC–AA should be chosen through an open competition that would allow for the comparison of the strengths and weaknesses of all interested accreditation organizations.

Commenters expressed support for either 3-year or 5-year terms for an ONC–AA. Some commenters suggested 5 years would provide more reliability and consistency. One commenter suggested an interim review of the ONC–AA after 3 years and granting an "extension" to 5 years based on the results of the review. One commenter suggested that an ONC–AA should not be allowed to "renew" its status at the end of the proposed 3-year term. The commenter contended that this would prevent an ONC–AA from overly

influencing how certification bodies are accredited. A commenter recommended that we begin accepting and reviewing requests for ONC–AA status sooner than 120 days prior to the expiration of the then-current ONC–AA's status and suggested 180 days as a possible alternative. The commenter reasoned that more time may be necessary to review and approve an ONC–AA. A couple of commenters requested clarification regarding how we would address concerns with an ONC–AA's operations and how we would remove or replace an ineffective ONC–AA.

Response. We do not believe that the use of an accreditor is unnecessary overhead. As stated in the Proposed Rule, we believe that accreditation (and the use of an accreditor) is the optimal and most practical approach for the long term because specialized accreditors in the private sector are better equipped to react effectively and efficiently to changes in the HIT market and to rigorously oversee the certification bodies they accredit. Further, the impartiality, knowledge, and experience of an accreditor will instill additional confidence in HIT developers, eligible professionals and eligible hospitals, and the general public regarding the ONC–ACB selection process. We believe that conformance to ISO 17011 is an appropriate measure to assess an accreditation organization's ability to perform accreditation under the permanent certification program, among the other submission requirements specified in § 170.503. ISO 17011 was developed by the International Organization for Standardization (ISO) and specifies the general requirements for accreditation bodies that accredit conformity assessment bodies. As noted in the Proposed Rule, an ONC–AA and the ONC–ACBs would be analogous to an accreditation body and the conformity assessment bodies, respectively, as referred to in ISO 17011. The introductory section of ISO 17011 explains that a system to accredit conformity assessment bodies is designed to provide confidence to the purchaser and the regulator through impartial verification that conformity assessment bodies are competent to perform their tasks. ISO 17011 and Guide 65 are standards that have been developed by a voluntary consensus standards body, as required by the National Technology Transfer and Advancement Act of 1995 and the Office of Management and Budget (OMB) Circular A–119, and we are aware of no alternative voluntary consensus standards that would serve the purpose for which these standards are intended to serve.

We appreciate the recommendations by the commenter, but we do not believe that it is necessary or appropriate to require an accreditation organization to be recognized under the NVCASE program or as a signatory to the International Accreditation Forum's MRA. It is our understanding that some of the requirements for recognition under the NVCASE program are similar to the requirements we have proposed for an accreditation organization to be approved as an ONC–AA. For example, the NVCASE Program Handbook states that the generic requirements for recognition as an accreditor are based on the ISO/IEC 17011 standard, and recognized accreditors of certification bodies must accredit those bodies to ISO/IEC Guide 65.[1] Therefore, we do not believe that a sufficient additional benefit would result from requiring accreditation organizations to be recognized under the NVCASE program. Adding such a requirement at this point may not provide sufficient notice and time for accreditation organizations that are not currently recognized by the NVCASE program to obtain NVCASE recognition in time to be eligible for approval as the ONC–AA at the start of the permanent certification program. Although we will not require an accreditation organization to be a signatory to the International Accreditation Forum's MRA, this information could be provided as part of an accreditation organization's detailed description of its accreditation experience to be included in its submitted request for ONC–AA status.

We agree with the commenters that, as proposed, granting ONC–AA status to only one accreditation body at a time is the best way to ensure consistency among ONC–ACBs. In addition, we believe that one ONC–AA will be able to address and support the needs of the market based on our projection of approximately 6 ONC–ACBs operating under the permanent certification program. We also agree with the commenter that suggested the ONC–AA should be chosen based on a competitive process that would allow us to evaluate all interested accreditation organizations in comparison to each other and select the organization that is best qualified to serve as the ONC–AA. Under the process we proposed, the National Coordinator would review requests for ONC–AA status in the order they are received and select as the ONC–AA the first accreditation organization that is deemed to be qualified based on the factors specified in § 170.503(b). We recognize the limitations of this approach in that it would prevent the National Coordinator from considering all of the requests for ONC–AA status that are submitted and selecting the accreditation organization that is found to be the best qualified in comparison to the entire pool of organizations that submitted requests for ONC–AA status. We believe that the permanent certification program would benefit from a more competitive approach to selecting the ONC–AA. A competitive process will ensure the best qualified organization that submits a request is chosen as the ONC–AA, which will improve the overall quality of the program and instill confidence in the general public as well as industry stakeholders.

We are revising § 170.503 to eliminate the provision for the National Coordinator to review requests for ONC–AA status in order of receipt and approve the first qualified accreditation organization. Instead, under this revised § 170.503, the National Coordinator will review all timely requests for ONC–AA status in one batch and choose the best qualified accreditation organization to serve as the ONC–AA. We are revising § 170.503(b) to provide a 30-day period during which all interested accreditation organizations may submit requests for ONC–AA status. We will publish a notice in the **Federal Register** to announce this submission period. We are revising § 170.503(c) to permit the National Coordinator up to 60 days to review all timely submissions and determine which accreditation organization is best qualified to serve as the ONC–AA based on the information provided in the submissions and each organization's overall accreditation experience. We originally proposed to permit the National Coordinator up to 30 days to review a request for ONC–AA status and make a decision. Based on the changes to the ONC–AA approval process, the National Coordinator will likely need more time to review and compare all of the requests for ONC–AA status in one batch and determine which accreditation organization is best qualified to be the ONC–AA out of a potential pool of multiple organizations. The National Coordinator will select the best qualified accreditation organization as the ONC–AA on a preliminary basis and subject to the resolution of the reconsideration process in § 170.504. The accreditation organization that is selected on a preliminary basis is not

[1] National Institute of Standards and Technology, U.S. Dep't of Commerce, NVCASE Program Handbook, NISTIR 6440 2004 ED (Dec. 2004), *available at http://gsi.nist.gov/global/index.cfm/L1-4/L2-38.*

permitted to represent itself as the ONC–AA or perform any accreditation(s) under the permanent certification program, unless and until it is notified by the National Coordinator that it has been approved as the ONC–AA on a final basis. All other accreditation organizations will be notified that their requests for ONC–AA status have been denied.

Any accreditation organization that submits a timely request for ONC–AA status and is denied may request reconsideration of that decision pursuant to § 170.504. In order to request reconsideration under revised § 170.504(b), an accreditation organization must submit to the National Coordinator, within 15 days of its receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC–AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC–AA status and that it would have been selected as the ONC–AA pursuant to § 170.503(c) if those errors had been corrected. Requests for reconsideration that are not received within the specified timeframe may be denied. We are revising § 170.504(c) such that the National Coordinator will have up to 30 days to review all timely submissions and determine whether an accreditation organization has met the standard specified in § 170.504(b) (*i.e.,* its submission has demonstrated that clear, factual errors were made in the review of its request for ONC–AA status and that it would have been selected as the ONC–AA pursuant to § 170.503(c) if those errors had been corrected). In determining whether an accreditation organization would have been selected as the ONC–AA, the National Coordinator will evaluate those accreditation organizations that demonstrate clear, factual errors, in comparison to each other as well as to the accreditation organization that was initially selected as the ONC–AA on a preliminary basis.

We are adding a new paragraph (d) to § 170.503 and revising § 170.504(d) such that if the National Coordinator determines that an accreditation organization has demonstrated that clear, factual errors were made in the review of its request for ONC–AA status and that it would have been selected as the ONC–AA pursuant to § 170.503(c) if those errors had been corrected, then that organization will be approved as the ONC–AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied. Conversely, if the National Coordinator determines that no accreditation organization has met the standard specified in § 170.504(b), then the organization that was initially selected as the ONC–AA on a preliminary basis will be approved as the ONC–AA on a final basis. An accreditation organization has not been granted "ONC–AA status" unless and until it is notified by the National Coordinator that it has been approved as the ONC–AA on a final basis, as stated in revised paragraph (f) of § 170.503.

We believe that it is appropriate to provide a 3-year term for an ONC–AA. A 5-year term may provide more consistency and reliability, but we believe a 3-year term provides an appropriate interval to fully assess an ONC–AA's performance under the permanent certification program and provide an opportunity for other interested organizations to seek ONC–AA status. We believe all interested accreditation organizations should be given the opportunity to request ONC–AA status when the National Coordinator is seeking to approve an ONC–AA. An interested accreditation organization should not be barred from "reapplying" simply because it previously served as an ONC–AA. Such a preclusion could prevent the National Coordinator from approving the best qualified accreditation organization or the only interested organization.

We agree with the commenter that we should begin to accept requests for ONC–AA status sooner than 120 days prior to the expiration of the then-current ONC–AA's status as we originally proposed. Similar to the commenter's recommendation, the National Coordinator will begin to accept requests for ONC–AA status at least 180 days prior to the expiration of the then-current ONC–AA's status. We believe this will give the market more time to transition to a new ONC–AA if we were to approve a different accreditation organization as the ONC–AA. We note, however, that if we were to approve a different accreditation organization as the ONC–AA, its status would not become effective until after the end of the then-current ONC–AA's term. As with the approval of the first ONC–AA and in accordance with the revised § 170.503(b), we will notify the public of the 30-day period for requesting ONC–AA status by publishing a notice in the **Federal Register**. Consistent with this discussion, we are revising § 170.503(f)(3) to specify that the National Coordinator will accept requests for ONC–AA status, in accordance with paragraph (b), at least 180 days before the then-current ONC–AA's status is set to expire.

As pointed out by the commenters, we did not propose a formal process for the National Coordinator to remove or take other corrective action against an ONC–AA that is performing poorly. We recognize that an ONC–AA, like an ONC–ACB, has significant responsibilities under the permanent certification program that are inextricably linked to the success of the permanent certification program. We agree with the commenters that a specified process for the National Coordinator to address poor performance or inappropriate conduct by an ONC–AA would be beneficial for the permanent certification program and would ensure that an ONC–AA is held accountable for its actions. Accordingly, we intend to issue a notice of proposed rulemaking (NPRM) that will address improper conduct by an ONC–AA, the potential consequences for engaging in such conduct, and a process by which the National Coordinator may take corrective action against an ONC–AA. We expect to issue this NPRM in the near future and do not believe it will unnecessarily delay the implementation of the permanent certification program.

2. On-Going Responsibilities

We proposed in § 170.503(e) that an ONC–AA would be required to, at minimum: Maintain conformance with ISO 17011; in accrediting certification bodies, verify conformance to, at a minimum, Guide 65; verify that ONC–ACBs are performing surveillance in accordance with their respective annual plans; and review ONC–ACB surveillance results to determine if the results indicate any substantive non-conformance with the terms set by the ONC–AA when it granted the ONC–ACB accreditation. We specifically requested public comment on these proposed responsibilities and whether there are other responsibilities that we should require an ONC–AA to fulfill.

Comments. A couple of commenters expressed agreement with the outlined responsibilities. One commenter suggested that the ONC–AA should provide annual reports of the results of their responsibilities. The commenter also recommended that the ONC–AA should review and/or audit all ONC–ACB processes, such as bylaws and standard operating procedures, no less than annually.

Response. We appreciate the expression of confidence in the ongoing responsibilities we have proposed for an ONC–AA. We also appreciate the commenter's recommendations for annual reports on the ONC–AA's

responsibilities and annual reviews and/or audits by the ONC–AA of all ONC–ACBs' processes. We believe, however, that annual reports from the ONC–AA are unnecessary. As stated above, the approval of an ONC–AA every three years will serve as a sufficient periodic review of the ONC–AA. There will also be opportunities to assess an ONC–AA's performance of its responsibilities at other junctures during the permanent certification program. The Principles of Proper Conduct for ONC–ACBs require ONC–ACBs to submit annual surveillance plans and to annually report surveillance results to the National Coordinator. Our review of an ONC–ACB's surveillance results should give an indication of whether the ONC–AA is performing its responsibilities to review ONC–ACB surveillance results and verify that ONC–ACBs are performing surveillance in accordance with their surveillance plans. We also expect that our review and analysis of surveillance plans and results will not only include feedback from the ONC–ACBs but also from the ONC–AA. The ONC–AA feedback will provide us with additional information on the ONC–AA's performance of its monitoring and review responsibilities related to ONC–ACB surveillance activities.

ISO 17011 specifies that an accreditation body (*i.e.,* an ONC–AA) shall require a conformance assessment body (*i.e.,* an ONC–ACB) to commit to fulfill continually the requirements for accreditation set by the accreditation body, cooperate as is necessary to enable the accreditation body to verify fulfillment of requirements for accreditation, and report changes that may affect its accreditation to the accreditor. ISO 17011 also contains provisions that require an ONC–AA to review an ONC–ACB periodically, but no less than every two years, and to do so in a manner prescribed under ISO 17011. Moreover, as one of its ongoing responsibilities, the ONC–AA will be required to verify that ONC–ACBs continue to conform to the provisions of Guide 65 at a minimum as a condition of continued accreditation. We believe these provisions will enable the ONC–AA to sufficiently oversee (*i.e.,* review and/or audit) the ONC–ACBs for the purposes of the permanent certification program. For instance, if the ONC–AA finds that an ONC–ACB is not in compliance with its accreditation requirements, then the ONC–ACB may lose its accreditation and subsequently its ONC–ACB status. The Principles of Proper Conduct for ONC–ACBs will also provide additional assurance that ONC–ACBs are operating in an acceptable manner under the permanent certification program.

We are revising § 170.503(e)(4) to state that the ONC–AA will be responsible for reviewing ONC–ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC–ACBs "with the conditions of their respective accreditations." We believe this clarification more accurately accounts for the possibility that different accreditation organizations may be approved to serve as the ONC–AA.

3. Reconsideration of Request for ONC–AA Status

We proposed in § 170.503(d) that an accreditation organization could appeal a decision to deny its request for ONC–AA status in accordance with § 170.504, but only if no other accreditation organization had been granted ONC–AA status. We proposed in § 170.504 to use generally the same procedures for reconsideration of an accreditation organization's request for ONC–AA status as we did for reconsideration of applications for ONC–ACB status with a few substantive distinctions. We proposed that an accreditation organization could ask the National Coordinator to reconsider a decision to deny its request for ONC–AA status only if no other accreditation organization had been granted ONC–AA status and it could demonstrate that clear, factual errors were made in the review of its request for ONC–AA status and that the errors' correction could lead to the accreditation organization obtaining ONC–AA status. We proposed that an accreditation organization that wished to contest its denial would be required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its request for ONC–AA status and explaining with sufficient documentation what factual error(s) it believes can account for the denial. We proposed that if the National Coordinator did not receive the accreditation organization's written statement within the specified timeframe that its request for reconsideration could be rejected. We proposed that the National Coordinator would have up to 15 days to consider a timely reconsideration request. We further proposed that if, after reviewing an applicant's reconsideration request, the National Coordinator determined that the applicant did not identify any factual errors, that correction of those factual errors would not remove all identified deficiencies, or that a qualified ONC–AA had already been approved, the National Coordinator could reject the applicant's reconsideration request and that this decision would be final and not subject to further review.

We did not receive any comments on these provisions. We are, however, revising § 170.503(c) and (d) and § 170.504 consistent with the changes we discussed earlier in this section of the preamble.

E. Correspondence

We proposed in § 170.505 to require applicants for ONC–ACB status and ONC–ACBs to correspond and communicate with the National Coordinator by e-mail, unless otherwise necessary. We proposed that the official date of receipt of any e-mail between the National Coordinator and an applicant for ONC–ACB status or an ONC–ACB would be the day the e-mail was sent. We further proposed that in circumstances where it was necessary for an applicant for ONC–ACB status or an ONC–ACB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt would be the date of the delivery confirmation.

We did not receive any comments on these proposals. We are, however, revising § 170.505 to include "or an ONC–ACB" in paragraph (b) to clarify that either an applicant for ONC–ACB status or an ONC–ACB may, when necessary, utilize the specified correspondence methods. This reference was inadvertently left out of § 170.505(b) in the Proposed Rule. We are also revising this section to apply the correspondence requirements to accreditation organizations that submit requests for ONC–AA status and the ONC–AA. These organizations are similarly situated to applicants for ONC–ACB status and ONC–ACBs with respect to corresponding with ONC. In particular, with our revisions that establish a specific time period for submitting requests for ONC–AA status, application of § 170.505 to accreditation organizations requesting ONC–AA status will provide a clear understating of when a request will be deemed received by the National Coordinator. Overall, we believe that applying the correspondence requirements to accreditation organizations requesting ONC–AA status and the ONC–AA will increase the efficiencies of the permanent certification program and lessen the correspondence burden on these organizations.

F. Certification Options for ONC–ACBs

1. Distinction Between Testing and Certification

We stated in the Proposed Rule that there is a distinct difference between the "testing" and "certification" of a Complete EHR and/or EHR Module. We described "testing" as the process used to determine the degree to which a Complete EHR or EHR Module can meet specific, predefined, measurable, and quantitative requirements. We noted that such results would be able to be compared to and evaluated in accordance with predefined measures. In contrast, we described "certification" as the assessment (and subsequent assertion) made by an organization, once it has analyzed the quantitative results rendered from testing along with other qualitative factors, that a Complete EHR or EHR Module has met all of the applicable certification criteria adopted by the Secretary. We noted that qualitative factors could include whether a Complete EHR or EHR Module developer has a quality management system in place, or whether the Complete EHR or EHR Module developer has agreed to the policies and conditions associated with being certified (*e.g.,* proper logo usage). We further stated that the act of certification typically promotes confidence in the quality of a product (and the Complete EHR or EHR Module developer that produced it), offers assurance that the product will perform as described, and helps consumers to differentiate which products have met specific criteria from others that have not.

To further clarify, we stated that a fundamental difference between testing and certification is that testing is intended to result in objective, unanalyzed data. In contrast, certification is expected to result in an overall assessment of the test results, consideration of their significance, and consideration of other factors to determine whether the prerequisites for certification have been achieved. To illustrate an important difference between testing and certification, we provided the example that we recite below.

An e-prescribing EHR Module developer that seeks to have its EHR Module certified would first submit the EHR Module to be tested. To successfully pass the established testing requirements, the e-prescribing EHR Module would, among other functions, need to transmit an electronic prescription using mock patient data according to the standards adopted by the Secretary. Provided that the e-prescribing EHR Module successfully passed this test it would next be evaluated for certification. Certification could require that the EHR Module developer agree to a number of provisions, including, for example, displaying the EHR Module's version and revision number so potential purchasers could discern when the EHR Module was last updated or certified. If the EHR Module developer agreed to all of the applicable certification requirements and the EHR Module achieved a passing test result, the e-prescribing EHR Module would be certified. In these situations, both the EHR Module passing the technical requirements tests and the EHR Module vendor meeting the other certification requirements would be required for the EHR Module to achieve certification.

Comments. Multiple commenters asked for additional clarification for the distinction between testing and certification. Commenters were concerned that ONC–ACBs would have too much discretion related to certification. The commenters asserted that ONC–ACBs should only be empowered to assess whether adopted certification criteria have been met or whether other applicable policies adopted by the National Coordinator through regulation, such as "labeling" policies, have been complied with. Commenters expressed specific concern with one of our examples of potential qualitative factors, which was the need to have "a quality management system in place." The commenters suggested that a requirement to have a quality management system in place is vague and gives too much discretion to an ONC–ACB.

Response. Our response to these comments is similar to the response we provided in the Temporary Certification Program final rule due to similarities that exist between the two certification programs. We require as a Principle of Proper Conduct that ONC–ACBs shall maintain their accreditation, which will, at minimum, require ONC–ACBs to operate their certification programs in accordance with Guide 65. As noted above, the ONC–AA will be required to verify that ONC–ACBs continue to conform to Guide 65 at a minimum as a condition of maintaining their accreditation. Guide 65 specifies the requirements that an organization must follow to operate a certification program. Moreover, because Guide 65 states in section 4.6.1 that a "certification body shall specify the conditions for granting, maintaining and extending certification," we believe that it would be inappropriate to dictate every specific aspect related to an ONC–ACB's certification program operations. We understand the concerns expressed by commenters over our example of a "quality management system" as another factor that ONC–ACBs may choose to include, in accordance with Guide 65, as part of their certification requirements for assessing Complete EHRs and/or EHR Modules and have considered how to best address such concerns.

With respect to those commenters who requested that we clarify the purview of ONC–ACBs related to certification and expressed concerns about the level of discretion afforded to ONC–ACBs, we agree that additional clarity is necessary regarding our intent and expectations of ONC–ACBs as initially expressed in our discussion of the differences between testing and certification in the Proposed Rule. We believe commenters were expressing a concern that certification could include other factors beyond the certification criteria adopted by the Secretary in subpart C of part 170, which could prevent them from receiving a certification in a timely manner if they were not aware of those factors. We agree with commenters that this is a legitimate concern. We did not intend to convey through our examples that we would adopt additional requirements for certification in this final rule beyond the certification criteria adopted by the Secretary in subpart C of part 170 and the other requirements imposed on ONC–ACBs in subpart E of part 170.

We seek to make clear that the primary responsibility of ONC–ACBs under the permanent certification program is to certify Complete EHRs and EHR Modules, and potentially other types of HIT at some point in the future, in accordance with the certification criteria adopted by the Secretary. In consideration of the comments and the preceding discussion, we are adding new provisions to § 170.545 (paragraph (b)) and § 170.550 (paragraph (b)) to make it explicitly clear that an ONC–ACB must offer the option for a Complete EHR or EHR Module to be certified solely to the applicable certification criteria adopted by the Secretary and not to any additional certification criteria. In other words, if a developer makes a request for its Complete EHR or EHR Module to be certified solely to the applicable certification criteria adopted by the Secretary, an ONC–ACB cannot require the Complete EHR or EHR Module to be certified to any other certification criteria beyond those that have been adopted by the Secretary. In complying with such a request, the ONC–ACB would still be expected to issue

certifications in accordance with the requirements specified by subpart E of part 170 (for example, § 170.523(k)). As a matter of its own business practices, however, an ONC–ACB may decide to offer multiple options for the certification of HIT, some of which could potentially impose other requirements for certification or include additional certification criteria beyond what has been adopted by the Secretary. If an ONC–ACB chooses to offer multiple certification options for HIT, we expect it would be done consistent with the requirements of the ONC–ACB's accreditation. Additionally, in accordance with Guide 65, section 6, the ONC–ACB would be required to "give due notice of any changes it intends to make in its requirements for certification" and "take account of views expressed by interested parties before deciding on the precise form and effective date of the changes."

We note, however, that while we do not preclude an ONC–ACB from certifying HIT in accordance with its own requirements that may be unrelated to and potentially exceed the certification criteria adopted by the Secretary, such activities would not be within the scope of an ONC–ACB's authority granted under the permanent certification program and should not be considered to be endorsed or approved by the National Coordinator or the Secretary. Accordingly, we have added as a component of a new principle in the Principles of Proper Conduct for ONC–ACBs (discussed in more detail in section *O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status*) that any certifications that are based solely on the applicable certification criteria adopted by the Secretary at subpart C must be separate and distinct from any other certification(s) that are based on other criteria or requirements. To further clarify, HIT that meets the definition of a Complete EHR or EHR Module and is certified to the certification criteria adopted by the Secretary as well as to an ONC–ACB's own additional certification criteria must have its certified status as a Complete EHR or EHR Module noted separately and distinctly from any other certification the ONC–ACB may issue based on its own certification criteria. For example, an ONC–ACB should indicate that the HIT has been certified as a "Complete EHR in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services" and, if applicable, separately indicate that the HIT meets "XYZ certification criteria as developed and/or required by [specify certification body]."

2. Types of Certification

We proposed in § 170.510 that applicants for ONC–ACB status may seek authorization from the National Coordinator to perform Complete EHR certification, EHR Module certification, and/or certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

We received multiple comments on the types of certification that ONC–ACBs can and should perform. These comments were in direct response to our requests for public comments on whether ONC–ACBs should certify the integration of EHR Modules and on whether applicants for ONC–ACB status should be permitted to apply to certify only Complete EHRs designed for an ambulatory setting or only Complete EHRs designed for an inpatient setting.

a. Complete EHRs for Ambulatory or Inpatient Settings

We requested public comment in the Proposed Rule on whether the National Coordinator should permit applicants under the permanent certification program to seek authorization to certify only Complete EHRs designed for an ambulatory setting or, alternatively, only Complete EHRs designed for an inpatient setting. Under our proposal, an applicant seeking authorization to perform Complete EHR certification would be required to certify Complete EHRs designed for both ambulatory and inpatient settings.

Comments. We received comments ranging from support for providing the option for applicants to certify Complete EHRs for either ambulatory or inpatient settings to support for our proposal to require an ONC–ACB to perform certification for both settings. Some commenters thought that our proposal could stifle competition and expressed concern that there may not be enough entities capable of performing Complete EHR certification for both settings. These commenters stated that allowing for Complete EHR certification for either an ambulatory or inpatient setting could enhance competition and expedite certifications. Conversely, a few commenters stated that providing the option would multiply the National Coordinator's application workload and slow the authorization of ONC–ACBs. One commenter also thought that the option may lead to applicants for ONC–ACB status competing for limited resources, such as specialized staff for conducting certification.

Some commenters expressed concern that if the National Coordinator were to allow applicants to certify Complete EHRs for either ambulatory or inpatient settings, there would not be enough ONC–ACBs to certify Complete EHRs for each setting. Therefore, these commenters' support for the option was conditioned on the National Coordinator ensuring that there were an adequate number of ONC–ACBs for each setting. One commenter only supported giving ONC–ACBs an option to certify Complete EHRs for either ambulatory or inpatient settings if the option included certification of EHR Module level interactions necessary for the exchange of data between ambulatory and inpatient Complete EHRs.

Some commenters stated that the option could lead to "almost complete" EHRs, which could then lead to eligible professionals and eligible hospitals paying large sums for niche EHR Modules based on complicated certification criteria such as biosurveillance or quality reporting. One commenter asserted that under our current proposal an applicant for ONC–ACB status could seek authorization to certify EHR Modules that together would essentially constitute a Complete EHR for an ambulatory setting (or an inpatient setting). Therefore, the commenter contended that we should allow an applicant for ONC–ACB status the option to seek authorization to certify Complete EHRs for either ambulatory or inpatient settings because an applicant for ONC–ACB status could essentially choose that option by seeking all the necessary EHR Module authorizations for either ambulatory or inpatient settings.

Response. In the Temporary Certification Program final rule, based on the concerns expressed by the commenters, we determined that it was inappropriate under the temporary certification program to allow applicants for ONC–ATCB status to seek authorization to test and certify Complete EHRs for either only ambulatory settings or only inpatient settings. We stated that we would reconsider the option for the permanent certification program based on any additional comments we received on the proposed permanent certification program.

The comments discussed above include comments we received that were applicable to both the temporary certification program and the permanent certification program as well as comments focused solely on the permanent certification program. As mentioned, we discussed the comments that were applicable to the temporary

certification program in the Temporary Certification Program final rule. The comments that were focused solely on the permanent certification program did not contain any additional information or rationale that would cause us to conclude that the option to allow applicants for ONC–ACB status to seek authorization to certify Complete EHRs for only ambulatory settings or only inpatient settings would be appropriate for the permanent certification program. Accordingly, we are not permitting this option in the permanent certification program.

To address the commenters' concerns about "almost complete" EHRs, we reiterate that for EHR technology to be considered a Complete EHR, it must have been developed to meet, at a minimum, *all* of the applicable certification criteria adopted by the Secretary. For example, a Complete EHR for an ambulatory setting must have been developed to meet all of the certification criteria adopted at § 170.302 and § 170.304. Therefore, if we were to provide the option for ONC-ACBs to seek authorization to certify Complete EHRs for only ambulatory settings or only inpatient settings, the Complete EHRs that they certify must have been developed to meet all of the applicable certification criteria adopted by the Secretary.

We agree with the commenter that an applicant for ONC–ACB status could seek authorization to certify certain types of EHR Modules that together could potentially include all of the capabilities required by the applicable certification criteria for an ambulatory setting. The important distinction between the commenter's suggested approach and the option we proposed is that under the commenter's approach the ONC–ACB would not be able to issue a "Complete EHR certification" for a combination of EHR Modules because the ONC–ACB had not received authorization to certify Complete EHRs. Consequently, if a Complete EHR developer wanted to obtain Complete EHR certification, they could not seek such certification from an ONC–ACB that did not have authorization to grant Complete EHR certifications. We would assume that a potential applicant for ONC–ACB status would consider this impact on its customer base when determining what type of authorization to seek.

Consistent with this discussion, we are finalizing proposed § 170.510 without modification.

b. Integrated Testing and Certification of EHR Modules

In the Proposed Rule, we requested public comment on whether ONC–ACBs should be required to certify that any EHR Module presented by one EHR Module developer for testing and certification would properly work (*i.e.,* integrate or be compatible) with other EHR Modules presented by different EHR Module developers.

Comments. Multiple commenters stated that certifying EHR Modules based on their ability to integrate with one another is a worthwhile endeavor. These commenters stated that such certification would make it easier for eligible professionals and eligible hospitals to purchase certified EHR Modules that are compatible and could be used together to achieve meaningful use and could increase or improve interoperability among HIT in general. Conversely, many other commenters strongly disagreed with requiring EHR Modules to be certified for compatibility and raised various concerns. Overall, these commenters asserted that it would be technically infeasible as well as both logistically (*e.g.,* multiple certification sites and multiple EHR Module developers) and financially impractical to attempt to certify whether two or more EHR Modules were compatible given the huge and shifting numbers of possible combinations. Another concern indicated that a mandatory requirement for ONC–ACBs to perform this type of certification would be challenging for ONC–ACBs because the EHR Module concept as defined in regulation is relatively new and because there is limited available guidance and mature testing and certification processes for this type of certification. One commenter opined that certification was not necessary because EHR Module developers would likely strive for integration on their own as a marketing tool for their EHR Modules.

Some commenters suggested that EHR Modules could be certified as "integrated bundles." One commenter recommended that if we were to pursue any type of EHR Module-to-EHR Module integration, it should be no earlier than when we adopt the next set of standards, implementation specifications, and certification criteria, and then it should only be done selectively based on meaningful use requirements. Another commenter suggested that ONC–ACBs be given the option, but not be required, to determine if EHR Modules are compatible.

Response. We believe that including a mandatory provision requiring ONC–ACBs to certify whether two or more EHR Modules are compatible would not be prudent due to the various impracticalities that were raised by commenters. We arrived at the same conclusion for the temporary certification program as explained in the Temporary Certification Program final rule. We believe that requiring ONC–ACBs to certify EHR Module-to-EHR Module integration is inappropriate primarily because of the impracticalities pointed out by commenters related to the numerous combinations of EHR Modules that will likely exist and the associated technical, logistical, and financial costs of determining EHR Module-to-EHR Module integration. We also agree with the commenter who suggested that developers will choose, most likely selectively, to integrate their EHR Modules with other EHR Modules for the purposes of making their products more marketable. Consequently, we believe that the market through business decisions and agreements may work to achieve integration where necessary and beneficial.

An EHR Module developer or developers may present EHR Modules together as a pre-coordinated, integrated bundle for certification pursuant to § 170.550(e) for the purpose of satisfying the privacy and security certification criteria adopted at subpart C of part 170. An ONC–ACB, however, is only permitted to certify a pre-coordinated, integrated bundle of EHR Modules if it is capable of meeting all of the applicable certification criteria and would otherwise meet the definition of and constitute a Complete EHR. We assume that the EHR Module developer(s), for business and potentially other reasons, would have reconciled any compatibility issues among the constituent EHR Modules that make up the pre-coordinated, integrated bundle before the bundle is presented for testing and certification.

We note that nothing in this final rule precludes an ONC–ACB or other entity from offering a service to certify EHR Module-to-EHR Module integration. However, to be clear, although we do not require or specifically preclude an ONC–ACB from certifying EHR Module-to-EHR Module integration, any EHR Module-to-EHR Module certification performed by an ONC–ACB or other entity will be done without specific authorization from the National Coordinator and will not be considered part of the permanent certification program. We understand that certification for EHR Module-to-EHR Module integration may be advantageous in certain instances, but

we do not believe, based on the impracticalities discussed above, that we could set all the necessary parameters for certification of EHR Module-to-EHR Module integration.

Consistent with this discussion, we are finalizing proposed § 170.510 without modification.

G. ONC–ACB Application Process

1. Application

We proposed in § 170.520 that an application would need to be submitted to the National Coordinator and that the application would need to contain certain information to be considered complete. We also noted that applications would be made available on ONC's Web site and could be submitted by e-mail.

Similar to the temporary certification program, we proposed to require an applicant for ONC–ACB status to indicate on its application the type of certification it seeks authorization to perform under the permanent certification program. Consistent with proposed § 170.510, an applicant could indicate that it seeks authorization to certify Complete EHRs, EHR Module(s), and/or other types of HIT for which the Secretary has adopted certification criteria. If the applicant were to request authorization to certify EHR Module(s), we proposed to require the applicant to identify the type(s) of EHR Module(s) that it seeks to certify.

We proposed that an applicant must provide general identifying information, including the applicant's name, address, city, State, zip code, and Web site. We proposed that an applicant also must designate an authorized representative and provide the name, title, phone number, and e-mail address of the person who would serve as the applicant's point of contact. We proposed that an applicant must submit documentation confirming the applicant's accreditation by an ONC–AA. Lastly, we proposed that an applicant must submit an executed agreement to adhere to the "Principles of Proper Conduct for ONC–ACBs."

We proposed that if the Secretary adopts certification criteria for HIT other than Complete EHRs and EHR Modules, an ONC–ACB would be required to submit an addendum to its original application if it wished to request authorization to certify this other type of HIT. Additionally, we proposed that if a new organization wanted to be authorized to certify another type of HIT, it would need to follow the rules for becoming an ONC–ACB, including first receiving accreditation from an ONC–AA.

Comments. We received comments expressing agreement with the application requirements, including the need for an applicant to be accredited before it applies. One commenter suggested that if an organization fails to become accredited on the first attempt that the organization should be given another opportunity. Another commenter suggested that, similar to the temporary certification program, we institute a "proficiency examination" for "key personnel." The commenter stated that such a competency test, adherence to credentialing standards such as ASTM International 2659, or a more formal and ongoing personnel certification program in accordance with ISO 17024 may have long-term benefits for the permanent certification program. A commenter also requested clarification on what information the National Coordinator would deem sufficient to confirm the applicant's accreditation. The commenter suggested that a current letter of accreditation, as opposed to the re-submission of supporting documentation that was submitted previously to the ONC–AA, could fulfill the requirement to confirm an ONC–ACB's accreditation.

Response. We appreciate the support for the proposed application requirements. We wish to further clarify these requirements for applicants who seek authorization to certify EHR Modules. In addition to identifying the specific type(s) of EHR Module(s) that they wish to certify, these applicants are expected to identify as part of their application the certification criterion or criteria that they believe should be included within the scope of their authorization for the EHR Module(s) they have identified. We believe requiring applicants to provide this information will ensure that an applicant and the National Coordinator will have a shared understanding of the scope of the authorization requested by the applicant, which could otherwise be difficult to discern based solely on the name(s) or type(s) of EHR Module(s) that the applicant identifies in its application.

In response to the commenter, we note that the ONC–AA will develop and manage the accreditation process for organizations that intend to apply for ONC–ACB status, including the number of times an organization may attempt to become accredited. We appreciate the commenter's recommendation for ONC–ACB personnel to undergo competency testing and/or a formal credentialing program, and we understand the potential benefits associated with such requirements. We do not, however, believe that ONC should independently require personnel of applicants for ONC–ACB status to pass a certain exam or possess certain credentials before the applicant applies ONC–ACB status. We believe that accreditation by the ONC–AA will be sufficient to ensure that an applicant for ONC–ACB status will have personnel who are qualified to perform certifications of Complete EHRs, EHR Modules, and/or other types of HIT. Further, we will require ONC–ACBs to attend ONC mandatory training and to maintain training programs for their own personnel, which we believe are adequate measures to ensure that ONC–ACB personnel will remain competent. Lastly, to properly document an ONC–ACB applicant's accreditation, the applicant should provide a copy of its accreditation record consistent with the accreditation record that the ONC–AA must keep in accordance with section 7.14 of ISO 17011. We believe that a copy of the record will allow the National Coordinator to properly confirm the extent of an applicant's accreditation.

In the Temporary Certification Program final rule, we noted a commenter's suggestion that we should establish a process that would enable ONC–ATCBs to apply for additional authorization to test and certify additional types of EHR Modules. We declined to establish a process separate from the application process that we had proposed for the temporary certification program, but we indicated that we would consider whether an alternative process would be appropriate for the permanent certification program. In other words, if an ONC–ACB is authorized to certify a certain type(s) of EHR Module(s) and wants to expand the scope of its current authorization so that it may certify other types of EHR Modules, should there be a way for it to obtain this authorization without following the application process outlined in § 170.520. After considering this possibility, we have decided to adopt a more streamlined process for ONC–ACBs that want to expand the scope of their current authorization to include Complete EHRs, other types of EHR Modules, and/or other types of HIT if it becomes an option. In order to request additional authorization under this process, an ONC–ACB must specify in writing the type of authorization it is seeking (including, for EHR Module(s) authorization, identification of the certification criterion or criteria that it believes should be included within the scope of its authorization) and provide documentation of its current accreditation that would support the

type of authorization it seeks, as described in § 170.520(a) and (c), respectively. The ONC–ACB would not be required to resubmit the other information specified in § 170.520, unless any of that information had changed since it was last provided to ONC. In deciding whether to grant an ONC–ACB's request to expand the scope of its current authorization, the National Coordinator may also consider whether the ONC–ACB has completed any mandatory training as may be required by § 170.523(b), which would confirm whether the ONC–ACB is competent to certify the specific type(s) of HIT for which it seeks authorization. For example, an ONC–ACB that is authorized to certify a certain type of EHR Module may request authorization to certify other types of EHR Modules that may include different capabilities and thus implicate different certification criteria adopted by the Secretary. The National Coordinator may require the ONC–ACB to complete mandatory training to ensure that the ONC–ACB understands the test tools and test procedures used for testing to the different certification criteria and can competently certify the other types of EHR Modules. We believe a more streamlined process will benefit both ONC–ACBs and developers of Complete EHRs, EHR Modules, and other types of HIT because it will enable ONC–ACBs to expand the scope of their authorization more efficiently and consequently provide additional certification services to developers. Overall, we believe this could potentially benefit the market for HIT by increasing the speed with which certified Complete EHRs, EHR Modules and potentially other types of HIT are available for purchase and/or implementation.

We are revising § 170.520(c) such that the documentation provided by the applicant must confirm that the applicant has been accredited by "the ONC–AA," instead of "an ONC–AA" as proposed. We believe the revision more clearly reflects that there will be only one ONC–AA at a time.

2. Principles of Proper Conduct for ONC–ACBs

We received multiple comments on the proposed Principles of Proper Conduct for ONC–ACBs. Many of those comments were also relevant to the proposed Principles of Proper Conduct for ONC–ATCBs because several identical Principles were proposed for both ONC–ACBs and ONC–ATCBs. As explained earlier in this preamble, given the similarities that exist between the temporary and permanent certification programs, the responses we provide below are often similar or identical to our responses to comments on the proposed Principles of Proper Conduct for ONC–ATCBs that we provided in the Temporary Certification Program final rule.

We did not receive any comments on the Principles of Proper Conduct proposed in paragraphs (b), (c) and (d) of § 170.523. Therefore, we are finalizing these Principles of Proper Conduct without modification. While we received comments on all of the other proposed Principles of Proper Conduct for ONC–ACBs and suggestions for additional principles of proper conduct, the majority of the comments were focused on or related to the proposed Principles that would require ONC–ACBs to provide ONC, no less frequently than weekly, a current list of Complete EHRs and EHR Modules that have been certified; only certify HIT that has been tested by a NVLAP-accredited testing laboratory; and submit an annual surveillance plan and annually report surveillance results.

a. Maintain Accreditation

We proposed in § 170.523(a) that an ONC–ACB would be required to maintain its accreditation. As discussed earlier, the ONC–AA will be required as part of its ongoing responsibilities to verify that ONC–ACBs are continuing to operate in accordance with Guide 65 at a minimum in order to maintain their accreditation.

Comments. A few commenters expressed opinions that accreditation was an appropriate requirement for ONC–ACBs. One commenter recommended that we review the processes of other accreditation organizations such as the American National Standards Institute, the Joint Commission, and the ISO to assist in the development of the accreditation program for the permanent certification program, while another commenter recommended that we only require compliance with select, appropriate provisions of Guide 65 as part of accreditation instead of all of Guide 65.

Response. We have reviewed the processes of other accreditation organizations and have concluded, as proposed, that the standards developed by the ISO (specifically, ISO 17011 and Guide 65) should serve as the foundation for developing the accreditation element of the permanent certification program. In particular, we have stated that we expect the ONC–AA will accredit ONC–ACBs based on the guidelines specified in ISO 17011. Further, we believe that all of the provisions of Guide 65 would be applicable to the accreditation program and thus we proposed that accreditation would include verification of a certification body's conformance, at minimum, to Guide 65. We believe that requiring ONC–ACBs to be accredited will ensure that ONC–ACBs are qualified to perform certifications and will continue to be capable of properly performing certifications.

b. ONC Visits to ONC–ACB Sites

We proposed in § 170.523(e) to require an ONC–ACB to allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled) any certifications performed to demonstrate compliance with the requirements of the permanent certification program.

Comments. A commenter expressed agreement with our proposal stating that both scheduled and unannounced visits are appropriate. Another commenter stated that if visits are unannounced, then there can be no assurance that a certification will actually be underway upon the arrival of an ONC representative. Therefore, the commenter recommended that we should revise the requirement to require an ONC–ACB to respond within 2 business days to an ONC request to observe certification by providing the date, time, and location of the next scheduled certification. Another commenter recommended that all visits should be planned because staff may not be available and "clearances" may need to be arranged well in advance of a site visit. A commenter also stated that ONC observers for site visits would likely need to execute confidentiality and/or business associate agreements because some HIT developers treat their software screens and other elements as trade secrets.

Response. Our proposal gave us the option to conduct either scheduled or unannounced visits. After considering the comments, we believe it is appropriate to maintain both options, as we did in the context of the temporary certification program. If we determine that there is a specific certification that would be appropriate for us or our authorized agent(s) to observe, we may find it is more prudent to schedule a visit. However, to monitor compliance with the provisions of the permanent certification program and to maintain the integrity of the program, we believe that unannounced visits are appropriate. We anticipate that ONC "authorized agents" could potentially include individuals or entities under contract with ONC, personnel from an entity with which ONC has a regulatory relationship (*e.g.,* personnel from the

ONC–AA), or personnel from other Federal agencies with certification expertise (*e.g.,* NIST). We expect to establish ahead of time for ONC–ACBs the parameters around announced or unannounced on-site visits. In establishing these parameters, we expect ONC–ACBs to ensure that any "clearances" for ONC or its authorized agents are obtained in a timely manner given the possibility of an unannounced site visit. We also expect ONC–ACBs will take the necessary steps to address any potential confidentiality issues with their customers (for example, through a confidentiality agreement that would enable ONC and its authorized representatives to observe the certification of a customer's HIT). Therefore, we are finalizing this Principle of Proper Conduct with only a minor modification. We are revising § 170.523(e) to clarify that site visits will be conducted during normal business hours. This condition was inadvertently left out of the proposed provision, but is consistent with our original intent as shown in the proposed and final versions of the analogous provision for ONC–ATCBs.

c. Lists of Certified Complete EHRs and EHR Modules

i. ONC–ACB Lists

We proposed in § 170.523(f) to require an ONC–ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified which includes, at a minimum, the vendor name (if applicable), the date certified, the product version, the unique certification number or other specific product identification, and where applicable, the certification criterion or certification criteria to which each EHR Module has been certified.

Comments. Many commenters expressed appreciation for the proposed requirement and the proposed frequency for which the lists were to be updated. In relation to the information ONC–ACBs must report, a commenter specifically expressed support for making timely, complete, and useful information available to eligible professionals and eligible hospitals as they purchase and implement Certified EHR Technology that will enable them to attempt to demonstrate meaningful use.

Some commenters requested clarification and made recommendations for revisions to the provision. One commenter suggested that the provision should be revised to require an ONC–ACB to notify ONC within a week of successful certification of new Complete EHRs and/or EHR Modules. Additionally, the commenter contended that the proposed provision was unclear as to whether an ONC–ACB was required to send a complete, current list or only new additions and whether the list could be sent via e-mail. Another commenter suggested revising the provision to require an ONC–ACB to also report a current list of "applicants" and their status in the certification queue.

Response. As proposed and as already finalized for the temporary certification program, we will require ONC–ACBs to provide the National Coordinator, no less frequently than weekly, with a current list of Complete EHRs and/or EHR Modules that have been certified. We anticipate only requiring weekly updates, but ONC–ACBs are free to provide more frequent updates. We believe weekly updates are sufficient for providing current information to the public on the status of certified Complete EHRs and EHR Modules without placing an administrative burden on ONC–ACBs. In this regard, we have previously stated and continue to expect that ONC–ACBs will provide the information electronically, such as through e-mail. We also agree with the commenter that it would be unnecessary for an ONC–ACB to continue to report on previously certified Complete EHRs and/or EHR Modules and, therefore, only expect these weekly reports to include new certifications issued between the last weekly report and the newly submitted weekly report. Additionally, we do not believe any substantial benefit would result from requiring ONC–ACBs to report on the status of Complete EHRs and/or EHR Modules that are in the process of being certified. The time needed for the certification of Complete EHRs and EHR Modules will likely vary based on many factors and, in some cases, may not be completed due to various reasons. Therefore, we do not believe that the reporting of products in an ONC–ACB's queue should be a requirement at this time.

We agree with the commenter who indicated that useful information should be made available to eligible professionals and eligible hospitals as they decide which Certified EHR Technology to adopt. We note that much of the information that will be reported by ONC–ACBs will also be included in the Certified HIT Products List (CHPL) that will be made publicly available on ONC's Web site. After consideration of the public comments received and our own programmatic objectives, we will require ONC–ACBs to report information related to the two additional elements that we already finalized for ONC–ATCBs in the Temporary Certification Program final rule. Our intention in including these two additional elements is to make more information widely available about the technology that has been certified, which will benefit eligible professionals, eligible hospitals, and other interested parties who wish to adopt certified Complete EHRs and EHR Modules. The two additional elements that we will require ONC–ACBs to report are the clinical quality measures to which a Complete EHR or EHR Module has been certified and, where applicable, any additional software that a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary. As with the other information that ONC–ACBs must report, these two additional elements will enable eligible professionals and eligible hospitals to make better informed purchasing decisions, consistent with the commenter's suggestion.

The reporting of clinical quality measures to which a Complete EHR or EHR Module has been certified will enable an eligible professional or eligible hospital to identify and adopt a Complete EHR or EHR Module that includes the clinical quality measures they seek to implement. Knowledge of the additional software a Complete EHR or EHR Module has relied upon to demonstrate compliance with a certification criterion or criteria will be useful, and in some cases essential, for eligible professionals and eligible hospitals who are deciding which Complete EHR or EHR Module to adopt. Eligible professionals and eligible hospitals could use this information to assess whether a specific certified Complete EHR or EHR Module may be incompatible with their current information technology (IT) or would require them to install additional IT. We stress that this reporting requirement only relates to software that is *relied upon* by a Complete EHR or EHR Module to demonstrate compliance with a certification criterion or criteria adopted by the Secretary. We do not intend or expect this requirement to be construed as a comprehensive specifications list or similar type of inclusive list. Rather, as with the temporary certification program, our rationale for including this requirement is to ensure that eligible professionals and eligible hospitals who adopt a certified Complete EHR or EHR Module understand what is necessary for the Complete EHR or EHR Module to

operate in compliance with the certification criterion or criteria to which it was certified. For example, if a Complete EHR relied upon an operating system's automatic log-off functionality to demonstrate its compliance with this certification criterion, we would expect the operating system relied upon to be reported. Conversely, if a Complete EHR included its own automatic log-off capability, even though the Complete EHR may have been certified using a particular operating system, we would *not require* the operating system to be reported because it was not relied upon to demonstrate compliance with the certification criterion.

We are revising § 170.523(f) to correct an inadvertent reference to vendors of Complete EHRs or EHR Modules. As proposed, the section would require ONC–ACBs to report the names of certified Complete EHR or EHR Module vendors, if applicable. Our use of the word "vendor" was not intended to exclude information related to self-developers from the reporting requirements of § 170.523(f). Throughout the Proposed Rule and this final rule, we have collectively referred to self-developers and commercial vendors as "developers" of Complete EHRs and EHR Modules. Therefore, we are replacing "vendor" with "Complete EHR or EHR Module developer" in § 170.523(f)(1).

We also believe it would be helpful to clarify the specific information that should be reported with respect to pre-coordinated, integrated bundles of EHR Modules that are certified in accordance with § 170.550(e). ONC–ACBs are required by § 170.523(f)(4) to report the unique certification number or other specific product identification of Complete EHRs and EHR Modules that have been certified. They are also required by § 170.523(f)(7) to report, where applicable, the certification criterion or criteria to which each EHR Module has been certified. Based on these provisions, ONC–ACBs should identify and include in their reports to the National Coordinator: the pre-coordinated, integrated bundles of EHR Modules that they certify; the list of constituent EHR Modules that comprise each bundle; and, where applicable, identify for each constituent EHR Module the certification criterion or criteria to which that particular EHR Module has been certified.

Finally, as with the temporary certification program, we note that our required reporting elements constitute a minimum. We do not preclude ONC–ACBs from including in their weekly reports additional information that prospective purchasers and users of Complete EHRs and EHR Modules would find useful, such as specifying the Complete EHR or EHR Module's compatibility with other software or compatibility with other EHR Modules. If not reported to the National Coordinator, we encourage ONC–ACBs to consider making such information available on their own Web sites to better inform prospective purchasers and users of Complete EHRs and EHR Modules.

We are revising § 170.523(f) consistent with our discussion above.

ii. Certified HIT Products List

We stated in the Proposed Rule that in an effort to make it easier for eligible professionals and eligible hospitals to cross-validate that they have in fact adopted Certified EHR Technology, the National Coordinator intends to make a master CHPL of all Complete EHRs and EHR Modules certified by ONC–ACBs available on the ONC Web site. The CHPL would be a public service and would be a single, aggregate source of all the certified product information ONC–ACBs provide to the National Coordinator. The CHPL would also represent all of the Complete EHRs and EHR Modules that could be used to meet the definition of Certified EHR Technology. We also noted that, over time, we anticipate adding features to the Web site, which could include interactive functions to help eligible professionals and eligible hospitals determine whether a particular combination of certified EHR Modules could potentially qualify as Certified EHR Technology.

Comments. Many commenters expressed support for our decision to create a list of certified Complete EHRs and EHR Modules and to post a link to that list on our Web site. Many commenters also provided recommendations for how to enhance the list. One commenter endorsed an online system whereby physicians could type in or select information on the Complete EHR or EHR Module they planned on using to determine whether their selected combination would enable them to meet the CMS Medicare and Medicaid EHR Incentive Programs requirements. The commenter reasoned that the steps were necessary because eligible professionals, especially in smaller practices, did not have the technical expertise or support to ascertain whether or not a Complete EHR, EHR upgrades, EHR Module(s), or a combination of EHR Modules would enable them to perform the meaningful use requirements. Another commenter requested an explicit commitment from ONC that the use of certified Complete EHRs and/or EHR Modules on the CHPL will support their ability to report all required meaningful use measures.

Some commenters expressed a preference that the CHPL contain information on the capabilities of certified Complete EHRs and EHR Modules associated with adopted certification criteria. Other commenters requested that the CHPL contain information on whether certified Complete EHRs or EHR Modules are compatible with other types of HIT. In particular, commenters stated that it was important to eligible professionals and eligible hospitals for Complete EHR and EHR Module developers to fully disclose the functions for which their products are certified, which software components are necessary to meet certification criteria, and to also fully disclose any compatibility issues. A few commenters also suggested that the CHPL contain data on usability features of certified Complete EHRs and EHR Modules.

One commenter recommended that ONC and each ONC–ACB maintain a list of certified Complete EHRs and EHR Modules. Another commenter recommended that, in order to prevent the conveyance of potentially inaccurate information and confusion in the market, an ONC–ACB should not maintain on its own Web site a current list of the Complete EHRs and/or EHR Modules that it has certified, but instead reference the CHPL on ONC's Web site for the complete list of certified Complete EHRs and EHR Modules.

Response. We appreciate the commenters' support for the CHPL and their recommendations for its enhancement. As previously explained in the Temporary Certification Program final rule, we intend for the CHPL to be a single, aggregate source of all certified Complete EHRs and EHR Modules reported by ONC–ACBs to the National Coordinator. The CHPL will include all of the certified Complete EHRs and EHR Modules that could be used to meet the definition of Certified EHR Technology. It will also include the other pertinent information we require ONC–ACBs to report to the National Coordinator, such as a certified Complete EHR's version number. Eligible professionals and eligible hospitals that elect to use a combination of certified EHR Modules may also use the CHPL webpage to validate whether the EHR Modules they have selected satisfy all of the applicable certification criteria that are necessary to meet the definition of Certified EHR Technology. The CHPL webpage will include a unique identifier (*e.g.,* an alphanumeric

identifier) for each certified Complete EHR and each combination of certified EHR Modules that meets the definition of Certified EHR Technology. The unique identifier provided by the CHPL webpage could subsequently be used to submit to CMS for attestation purposes.

Consistent with the temporary certification program, we believe that only ONC should maintain the CHPL to ensure that the CHPL is accurate and comprehensive. However, we do not believe that it is appropriate to preclude an ONC–ACB from maintaining on its own Web site a list of Complete EHRs and/or EHR Modules that it certified. An ONC–ACB's own list could have benefits for the market in identifying the specific ONC–ACB that certified a Complete EHR or EHR Module. The ONC–ACB may also create a link on its Web site to the CHPL, which conceivably would be a user-friendly feature.

d. Records Retention

We proposed in § 170.523(g) to require an ONC–ACB to retain all records related to the certification of Complete EHRs and/or EHR Modules for a minimum of 5 years.

Comments. Commenters recommended that our records retention requirement be consistent with CMS's requirement for eligible professionals and eligible hospitals who seek to qualify for Medicare or Medicaid incentive payments for meaningful use, plus an additional two years to ensure that records are available during an audit process.

Response. As stated in the Proposed Rule, the record retention requirement is based on our consultations with NIST regarding standard industry practice. As also stated in the Proposed Rule, the purpose of our records retention requirement is twofold. An ONC–ACB's records would be directly relevant to a determination by the National Coordinator that the ONC–ACB committed a Type-2 violation and/or to revoke the ONC–ACB's status. Second, ONC–ACBs' certification records will likely be necessary for ONC–ACBs to conduct surveillance under the permanent certification program. In addition to the records retention requirement of § 170.523(g), ONC–ACBs are expected to retain records consistent with the terms of their accreditation, which will include the requirements of Guide 65. Lastly, our records retention requirement should be construed as an independent requirement and is not intended to replace or supplant any other requirements imposed by law or otherwise agreed to by ONC–ACBs. Accordingly, we will, as proposed, require ONC–ACBs to retain all records related to the certification of Complete EHRs and/or EHR Modules for a minimum of 5 years.

e. NVLAP-Accredited Testing Laboratory

In the Proposed Rule, we proposed to separate the responsibilities for testing and certification in the permanent certification program. We proposed that the National Coordinator's authorization granted to ONC–ACBs under the permanent certification program would not extend to the testing of Complete EHRs or EHR Modules. Instead, we proposed that the National Voluntary Laboratory Accreditation Program (NVLAP), as administered by NIST, would be responsible for accrediting testing laboratories and determining their competency. In this role, NVLAP would be solely responsible for overseeing accreditation activities related to testing laboratories for purposes of the permanent certification program. We mentioned NVLAP's experience with developing specific laboratory accreditation programs (LAPs) for testing and calibration laboratories in response to legislative or administrative actions, requests from government agencies or, in special circumstances, from private sector entities. We proposed that the National Coordinator would decide whether to issue a request to NVLAP to develop a LAP for testing laboratories after considering public comments on our proposals for the permanent certification program. To ensure that ONC–ACBs review test results from legitimate and competent testing laboratories, we further proposed in § 170.523(h) to require ONC–ACBs to only certify HIT, including Complete EHRs and/or EHR Modules, that has been tested by a NVLAP-accredited testing laboratory.

We received a number of comments on these proposals and have divided them into two categories: Separation of testing and certification; and accreditation, test tools and test procedures, and ONC–ACBs' permitted reliance on certain test results.

i. Separation of Testing and Certification

Comments. Commenters expressed general support for our proposal to establish a permanent certification program that includes the use of independent, accredited testing laboratories. Commenters stated that the separation of the testing and certification processes will provide more transparency and result in a more rigorous permanent certification program. Conversely, a few commenters were not certain that separation or an accredited testing process were even necessary. One of these commenters was concerned that separation would lead to increased costs, particularly for self-developers that will require on-site testing and certification. Another commenter was concerned that separation, if not managed properly, could unintentionally result in confusion and delay the certification of HIT products. Although a commenter assumed that HIT products will be tested before they are certified, the commenter noted that we did not clearly delineate the order of testing and certification in the Proposed Rule.

Response. We appreciate the comments of support for our proposal to separate the testing process from the certification process in the permanent certification program. We believe that the separation of testing laboratories and certification bodies is appropriate because it will result in a more transparent and demanding permanent certification program, as the commenters noted. We also believe these program qualities will be enhanced by the use of specialized accreditation organizations from the private sector to accredit the certification bodies that ultimately will become ONC–ACBs. As discussed in the Proposed Rule, these accreditation organizations will be better equipped than ONC to react effectively and efficiently to changes in the HIT market and rigorously oversee the certification bodies they accredit. Additionally, as noted in the Proposed Rule, we have observed in other industries, such as the manufacturing of water-conserving products, that testing and certification processes are typically handled independently and separately.

We expect that the separation of testing and certification will be managed properly by accredited testing laboratories and ONC–ACBs, respectively, and will not lead to undue delays or confusion. If necessary, we may issue program guidance at some point in the future in order to address questions or confusion about the elements and processes of the permanent certification program as well as the eventual transition from testing and certification under the temporary certification program. As for possible delays, we believe that any customer and/or product could experience delays under a testing and certification program for various reasons, but we do not anticipate any undue delays that would be specifically attributable to the separation of testing and certification under the permanent certification program. We expect that the ONC–ACBs

and accredited testing laboratories, having achieved accreditation, will have the ability to manage requests for certification and testing, respectively, in a timely manner. We also expect that these bodies will be able to answer questions about requests for certification and/or testing, as applicable, and provide other guidance to HIT developers based on the training and instruction they receive from ONC and NVLAP.

We appreciate the commenter's concern about the potential costs of testing and certification. The commenter seems to suggest that the costs associated with the testing and certification of Complete EHRs and EHR Modules will be higher because of the separation of the testing and certification processes, particularly for self-developers. We agree that the costs to Complete EHR and EHR Module developers could potentially increase due to the separation of the testing and certification processes, but we believe that any potential increases will not be prohibitive for developers. Our Regulatory Impact Analysis (RIA) in both the Proposed Rule and this final rule accounts for potential cost increases due to the separation of the testing and certification processes. The RIA states that our estimated costs for the testing and certification of Complete EHRs and EHR Modules under the permanent certification program include the costs of separate testing and certification as well as on-site testing and certification. We have provided a range for the potential costs of testing and certification under the permanent certification program. We did not receive any comments demonstrating that the costs associated with testing and certification will be higher than our estimates in the Proposed Rule because of the separation of the testing and certification processes. In addition, the actual costs of testing and certification may be lower than our estimates due to factors such as competitive pricing and/or lower costs attributable to gap certification. We further discuss the processes and costs associated with gap certification in section *P. Differential or Gap Certification* and in the RIA. Lastly, we note that ONC–ACBs may also become accredited testing laboratories under the permanent certification program, which may result in costs savings for developers that choose to have their Complete EHR and/or EHR Module tested and certified by the same organization.

The commenter correctly assumed that Complete EHRs and EHR Modules must first be tested before they can be certified under the permanent certification program. As we discussed in the Proposed Rule and this final rule, the concept of "certification" requires an ONC–ACB to analyze the quantitative results of testing and subsequently assess whether a Complete EHR or EHR Module has met all of the applicable certification criteria adopted by the Secretary. The chronological order of testing and certification is also addressed in § 170.523(h), which requires an ONC–ACB to only certify HIT that has been tested in accordance with the provisions of that section. For these reasons, it would be impracticable for a Complete EHR or EHR Module to be certified by an ONC–ACB before it undergoes testing.

ii. Accreditation, Test Tools and Test Procedures, and ONC–ACBs' Permitted Reliance on Certain Test Results

Comments. Commenters generally requested more information about the accreditation of testing laboratories under the permanent certification program. One commenter asked whether NVLAP will develop a specific field of accreditation for EHR technology and whether it will provide an application for entities interested in becoming an accredited testing laboratory. Another commenter supported our proposal to ask NVLAP to develop a LAP and requested that the LAP be designed specifically for Complete EHR and EHR Module testing. Commenters requested that we provide detailed information explaining how ONC and NIST will coordinate efforts to ensure that the accredited testing laboratories overseen by NVLAP are established within a timeframe that is consistent with ONC's efforts to authorize certification bodies. The commenters also requested information explaining how it will be determined whether testing laboratories have sufficient technical expertise and capacity to support the demand for testing in a timely manner. Many commenters recommended that testing laboratories be required to offer remote and on-site testing. Additionally, a commenter requested guidance as to how an ONC–ACB would know that a testing organization is NVLAP-accredited and suggested listing NVLAP-accredited testing laboratories on ONC's Web site as a reasonable solution.

Response. As discussed in the Proposed Rule, section 3001(c)(5) of the PHSA authorizes the National Coordinator, in consultation with the Director of NIST, to establish a program or programs for the voluntary certification of HIT, and such program(s) "shall include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act." Section 13201(b) of the HITECH Act provides that the Director of NIST, in coordination with the HIT Standards Committee, "shall support the establishment of a conformance testing infrastructure * * *," the development of which "may include a program to accredit independent, non-Federal laboratories to perform testing." Consistent with this statutory authority, we are finalizing our proposal that NVLAP, as administered by NIST, will be responsible for establishing and managing a program for the accreditation of laboratories to perform HIT testing under the permanent certification program.

As noted in the Proposed Rule, we are confident that NVLAP has the necessary scientific staff with specialized technical capabilities to develop an accreditation program for the testing of HIT. NVLAP has been responsible for developing a biometrics LAP for the Department of Homeland Security, a program to accredit laboratories for conducting security evaluations for the National Security Agency, a program to accredit laboratories to test hardware and software for voting systems, as well as many other programs for accrediting testing laboratories in response to Federal agencies' requests. Additionally, NIST scientific staff has exhibited their expertise with HIT by developing the test tools and test procedures for the temporary certification program. Based on our discussions with NIST, these experts will also be involved in developing the LAP for the permanent certification program. Given the demonstrated scope of NVLAP's and NIST's technical expertise, the National Coordinator will request that NVLAP develop a LAP specifically for HIT and the permanent certification program. The National Coordinator anticipates that the LAP will align with the programmatic goals of the permanent certification program, including the program's current focus on EHR technology.

We are currently working closely with NIST to achieve programmatic objectives related to the testing of Complete EHRs and EHR Modules under the temporary certification program. We expect this close relationship and degree of coordination will extend into the permanent certification program as the HIT LAP is developed. To further align our efforts with NIST, we are issuing this final rule a year in advance of the anticipated sunset of the temporary certification program and the start of testing and certification under the permanent certification program. During this period

of time, we expect NVLAP will develop the HIT LAP for the permanent certification program after receiving the National Coordinator's request and will subsequently begin the accreditation of testing laboratories. We also expect to complete the process of approving the ONC–AA during this timeframe, which will enable certification bodies to attempt to become accredited and apply for ONC–ACB status.

We anticipate that NVLAP, based on their aforementioned experience in developing other LAPs, will develop a LAP for the permanent certification program that will ensure accredited testing laboratories have the necessary technical expertise and the capacity to support market demand. We also anticipate that NVLAP will take into account current HIT industry testing practices and market demands, such as the use of remote testing and the need for on-site testing in some instances, when developing the LAP for accrediting testing laboratories. Even if the LAP developed by NVLAP does not expressly address remote and/or on-site testing, we expect accredited testing laboratories would offer such testing options if there was market demand. Lastly, as the commenter recommended, we expect to coordinate efforts with NIST and NVLAP to ensure that the public is made aware of NVLAP-accredited testing laboratories by listing them on our respective Web sites and identifying them through other appropriate means.

Comments. Commenters requested more specificity about the development and implementation of test tools, test procedures, and test scripts. Commenters requested clarity as to whether NIST, the accredited testing laboratories, or another entity would be responsible for developing the test tools and test procedures. One commenter stated that if NIST would be responsible, then NIST should provide information on how it will address the testing of open source Complete EHRs and EHR Modules. Some commenters recommended that a collaborative process be used in the development and implementation of test tools and test procedures. A commenter suggested that we create an advisory body for the development of test tools and test procedures, while other commenters suggested that consultations with Standards Development Organizations (SDOs) should be a requirement. One commenter recommended the use of the EHR System Functional Model (EHR–S FM). Alternatively, most commenters simply requested an open, transparent and industry consensus-based approach to developing and implementing test methods that allows for a user-friendly feedback process. Another commenter requested that we ensure that states be prohibited from requiring separate and additional testing processes.

Response. We can assure commenters that, as with the temporary certification program, only test tools and test procedures that have been approved by the National Coordinator can be used to test Complete EHRs, EHR Modules and potentially other types of HIT in order for them to be eligible for certification by an ONC–ACB under the permanent certification program. This requirement is imposed on ONC–ACBs under § 170.523(h). We believe by having the National Coordinator approve test tools and test procedures, we will ensure the best test tools and test procedures are utilized. We also believe the National Coordinator's approval will instill greater certainty and confidence in developers and users of Complete EHRs, EHR Modules and other types of HIT. Lastly, we believe that by having the National Coordinator approve the test tools and test procedures for the permanent certification program, we can provide greater consistency in the testing of Complete EHRs, EHR Modules and potentially other types of HIT.

In the Temporary Certification Program final rule, we adopted a process for approving test tools and test procedures, and we intend to use this same process for the permanent certification program. For the permanent certification program, a person or entity may submit a test tool and/or test procedure to the National Coordinator to be considered for approval to be used by NVLAP-accredited testing laboratories. The submission should identify the developer of the test tool and/or test procedure; specify the certification criterion or criteria that is/are addressed by the test tool and/or test procedure; and explain how the test tool and/or test procedure would evaluate a Complete EHR's, EHR Module's, or if applicable, other type of HIT's compliance with the applicable certification criterion or criteria. The submission should also provide information describing the process used to develop the test tool and/or test procedure, including any opportunity for the public to comment on the test tool and/or test procedure and the degree to which public comments were considered. In determining whether to approve a test tool and/or test procedure for purposes of the permanent certification program, the National Coordinator will consider whether it is clearly traceable to a certification criterion or criteria adopted by the Secretary; whether it is sufficiently comprehensive (*i.e.,* assesses all required capabilities) for NVLAP-accredited testing laboratories to use in testing a Complete EHR's, EHR Module's, or other type of HIT's compliance with the certification criterion or criteria adopted by the Secretary; whether an appropriate public comment process was used during the development of the test tool and/or test procedure; and any other relevant factors. When the National Coordinator has approved test tools and/or test procedures for purposes of the permanent certification program, we will publish a notice of availability in the **Federal Register** and identify the approved test tools and test procedures on the ONC Web site.

Once test tools and test procedures have been approved by the National Coordinator, we expect NVLAP-accredited testing laboratories will have some degree of responsibility and flexibility to configure their own test scripts (*i.e.,* specific scenarios using the approved test tools and test procedures). This could involve, for example, the creation of a testing sequence that a NVLAP-accredited testing laboratory believes is the most efficient way to test a certain suite of capabilities. Of course, this responsibility and flexibility may be constrained by the accreditation requirements applicable to the NVLAP-accredited testing laboratories. Given the level and types of adjustments that have been made by ONC–ATCBs for the temporary certification program, we do not believe that it will be possible for NVLAP-accredited testing laboratories to include significant variations in their test scripts such that a Complete EHR or EHR Module will pass a test administered by one laboratory but fail a test administered by a different laboratory.

Based on our stated approach to the development of test tools and test procedures under the permanent certification program, we do not believe that an advisory board will be necessary for the development of test tools and test procedures. In deciding whether to approve specific test tools and test procedures, the National Coordinator will consider whether public feedback was a part of the process for developing those tools and procedures. Although public feedback could take many different forms, we expect it might potentially include some or all of the methods that were mentioned by the commenters (*e.g.,* transparent processes, collaborative and HIT industry consensus-based approaches, consultations with SDOs, and/or utilization of EHR–S FM). In response to commenters' questions about NIST's

role in the development of test tools and test procedures, we anticipate that many of the test tools and test procedures that were developed by NIST and approved for the temporary certification program will likely be applicable to and may be approved for use in performing testing under the permanent certification program, particularly if the adopted certification criteria have not been revised when testing begins under the permanent certification program. As for the future development of test tools and test procedures, we expect to continue to consult with NIST in the development of test tools and test procedures as needed for the testing of HIT to new and/or revised certification criteria adopted by the Secretary. In addition, as previously discussed, any person or entity may submit test tools and test procedures for the National Coordinator's consideration for use in the permanent certification program. We expect that open source Complete EHRs and EHR Modules will be tested in the same manner as proprietary Complete EHRs and EHR Modules because we intend for them to be certified in the same manner as proprietary Complete EHRs and EHR Modules. Lastly, we are not familiar with State law requirements that may be applicable to testing laboratories and thus are unable to provide a fully informed response to the commenter's suggestion.

Comments. Commenters recommended that only one accreditor be permitted to accredit testing laboratories in order to ensure consistency in the accreditation process. Multiple commenters supported the recognition of NVLAP as the accreditor, pointing out that NVLAP is an internationally recognized testing laboratory accreditation program, while other commenters objected to the use of NVLAP as the sole accreditor. The commenters stated that there are at least 4 laboratory accreditation bodies in the United States that are considered equivalent to NVLAP under the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). The commenters asserted that, as a signatory to the ILAC MRA, NVLAP is obligated to promote the acceptance of other signatories' accreditations as being equivalent to their own. Further, the commenters recommended that the current proposal for ONC–ACBs to certify only HIT that has been tested by a NVLAP-accredited testing laboratory should be rescinded and replaced with a principle of proper conduct that allows ONC–ACBs to certify HIT that has been tested by testing laboratories accredited by any ILAC MRA signatory. Possibly as an alternative approach, one of these commenters suggested that NVLAP could validate and acknowledge the other accreditations by ILAC MRA signatories and thereby authorize those accredited testing laboratories to conduct the testing of Complete EHRs and/or EHR Modules under the permanent certification program. The commenter asserted that such an approach would be consistent with the ILAC MRA.

Response. We strongly believe, as supported by the commenters, that consistency in accreditation will be an important element of the permanent certification program. We have already demonstrated our commitment to such consistency by concluding that there should be only one ONC–AA at a time. Similarly, we believe that there should be only one accreditor for testing laboratories under the permanent certification program. We believe NVLAP is the best qualified accreditation organization to fill the role of the sole accreditor for testing laboratories based on the reasons we articulated above in support of our decision to ask NVLAP to develop a HIT LAP for the permanent certification program.

We disagree with the commenters' suggestion that ONC–ACBs should be allowed to rely on testing results from laboratories that have been accredited by any signatory to the ILAC MRA. Although commenters stated that other accreditation bodies are considered to be equivalent to NVLAP based on the ILAC MRA, we are unable to independently verify this assertion and thus cannot rely on it for purposes of assessing the competence of other accreditation bodies. More importantly, as previously discussed, the use of multiple accreditation bodies may undermine our programmatic goal of ensuring consistency in accreditation. Further, considering that the National Coordinator intends to ask NVLAP to develop a HIT LAP, requiring ONC–ACBs to use test results from NVLAP-accredited testing laboratories will ensure accreditation is performed according to a LAP that the National Coordinator believes is appropriate for the permanent certification program. As for the commenter's suggestion that NVLAP could validate and acknowledge the accreditations of testing laboratories by ILAC MRA signatories, we believe such a decision would be within the purview of NVLAP. Under § 170.523(h), ONC–ACBs are only permitted to certify HIT that was tested by a NVLAP-accredited testing laboratory or, in certain circumstances, by an ONC–ATCB. For purposes of that section, a testing laboratory must be accredited by NVLAP in accordance with the HIT LAP that the National Coordinator will ask NVLAP to develop. NVLAP could decide to pursue the approach of validating or acknowledging the testing laboratory accreditations of ILAC MRA signatories. In order for an ONC–ACB to certify HIT that was tested by one of those testing laboratories, however, the testing laboratory must also receive a separate accreditation from NVLAP.

Consistent with this discussion, we are revising § 170.523(h) to state that an ONC–ACB may only certify HIT, including Complete EHRs and/or EHR Modules, that has been tested by a NVLAP-accredited testing laboratory using test tools and test procedures that have been approved by the National Coordinator. We are also revising § 170.523(h) to allow ONC–ACBs, under certain circumstances, to rely on testing that has been performed by ONC–ATCBs, which must also have been done using test tools and test procedures that have been approved by the National Coordinator. The circumstances when an ONC–ACB may rely on testing performed by an ONC–ATCB are more fully discussed under sections *O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status* and *P. Differential or Gap Certification* of this preamble.

f. Surveillance

We proposed that ONC–ACBs would be required to conduct surveillance of Complete EHRs and/or EHR Modules that they had previously certified. As part of its surveillance efforts, we proposed in § 170.523(i) to require an ONC–ACB to submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results. Noting that ONC–ACBs will be accredited to the requirements of Guide 65 at a minimum, we stated that we expect ONC–ACBs to perform surveillance in accordance with Guide 65 at a minimum, which in section 13 provides that the "certification body [or 'ONC–ACB'] shall periodically evaluate the marked [or 'certified'] products to confirm that they continue to conform to the [adopted] standards." We further clarified that this would require ONC–ACBs to evaluate and reevaluate previously certified Complete EHRs and/or EHR Modules to determine whether the Complete EHRs and/or EHR Modules they had certified in a controlled environment also performed in an acceptable, if not the same, manner in the field.

We proposed that the ONC–AA must have processes in place to ensure that the certification bodies it accredits properly conduct surveillance. In this regard, we stated that ONC–ACBs should be given the flexibility to conduct surveillance in accordance with their accreditation. We acknowledged that the HIT industry could potentially benefit from the development of common elements of surveillance and requested comments on what those elements should include as well as specific approaches to surveillance that have been successful in other industries and should be replicated for HIT. We indicated that we expected to issue annual guidance for ONC–ACBs identifying ONC's priorities regarding certain elements of surveillance that could be considered for inclusion in their surveillance plans.

We noted that we expected to use the results of ONC–ACB surveillance as feedback on the operations of the permanent certification program and to make information publicly available regarding the implementation and performance of Complete EHRs and EHR Modules in the field. We further noted that surveillance results could also be used by prospective purchasers of Complete EHRs and/or EHR Modules as a tool for evaluating specific products. We emphasized that surveillance results obtained by ONC–ACBs and reported to the National Coordinator would not immediately affect a Complete EHR or EHR Module's certification. We stated that, if after an ONC–ACB reevaluated a Complete EHR it had previously certified and reported that the Complete EHR no longer met a certification criterion or criteria because, for example, an individual had taken actions to alter a capability provided by the Complete EHR such that it no longer performed according to its original design or improperly installed the Complete EHR, such a result would not automatically invalidate the Complete EHR's certification. We also stated that we would expect ONC–ACBs upon the identification of a pattern of poorly performing previously certified Complete EHRs and/or EHR Modules to determine whether they had properly certified the Complete EHR or EHR Module in the past. Further, we requested public comment on whether the National Coordinator should consider taking proactive steps to protect purchasers of Complete EHRs and/or EHRs Modules through actions such as "de-certifying" Complete EHRs and/or EHR Modules if a pattern of unsatisfactory surveillance results emerges and the ONC–ACB has not taken any measures to evaluate the poor performance.

Comments. We received many comments related to surveillance with commenters supporting the concept of surveillance as well as offering recommendations for the focus/elements of surveillance plans. An overarching theme expressed in the comments was that surveillance conducted by ONC–ACBs under the permanent certification program should have uniform and consistent elements. Commenters expressed various opinions about the focus/elements of surveillance plans. One commenter noted that Guide 65, Section 13 does not specifically identify post-market surveillance of products that are being used by purchasers. This commenter also mentioned that Guide 65 is currently under review by ISO and requested clarification as to how the National Coordinator would address any changes to Guide 65. Another commenter expressed a concern that the term "surveillance" might be associated with FDA post-market activities of drugs and devices, which would suggest that surveillance involves the reporting of only adverse events. Therefore, the commenter suggested using the term "monitoring" to describe the surveillance process because the commenter asserted that "monitoring" better conveys the process of assessing the performance, and encouraging the adoption of, Certified EHR Technology. A commenter expressed concerns about surveillance from a practical perspective and gave the example that the surveillance of MRI or CT devices for radiation doses is of a different scope than overseeing the functionality of Certified EHR Technology. The commenter further asserted that, for clinical systems, it will be important that any type of surveillance activity to measure system safety not become overly prescriptive or stringent. Another commenter requested clarification of whether surveillance would be limited to the certified Complete EHR or EHR Module or extend to include the end user's use of the Complete EHR and EHR Module, including the assembly of certified EHR Modules into Certified EHR Technology.

Multiple commenters asserted that surveillance should focus only on adopted certification criteria and whether certified products meet the criteria in operation. Consistent with this position, commenters suggested that surveillance plans should contain elements such as testing whether certified Complete EHRs and EHR Modules are performing in "live" environments as certified, ensuring that Complete EHR and EHR developers "label" certified Complete EHRs and EHR Modules according to their certifications, and monitoring that the versions of Complete EHRs and EHR Modules that are being used are certified versions. Some commenters suggested that surveillance could assess patient and/or provider satisfaction. More specifically, commenters suggested that surveillance could attempt to assess eligible professionals' and eligible hospitals' success in achieving meaningful use with the certified Complete EHRs and EHR Modules. However, many commenters recognized that surveillance of concepts such as satisfaction and success would implicate additional variables, such as training and implementation, as well as other factors such as subjective observations.

Response. Our proposed approach to surveillance was based on the concept that eligible professionals and eligible hospitals must be able to rely on the certifications that are issued by ONC–ACBs. ONC–ACBs have a responsibility to ensure that the certifications they issue serve as an indication of a Complete EHR and/or EHR Module's capabilities and compliance with the certification criteria adopted by the Secretary. We expect ONC–ACBs, consistent with their accreditation and Guide 65, to conduct surveillance of the Complete EHRs and/or EHR Modules they have previously certified. An ONC–ACB would focus its surveillance activities on whether the Complete EHRs and/or EHR Modules it has certified continue to perform "in the field" or in a "live" environment as they did when they were certified. Many commenters understood this to be the scope of our proposal and agreed with this approach. Other commenters, however, suggested that we consider other aspects of performance that are less directly related to whether a previously certified Complete EHR or EHR Module continues to perform in a manner consistent with its certification (*e.g.,* the assessment of a provider's success in achieving meaningful use). While we appreciate these additional suggestions, we do not believe that they are appropriate to include as requirements for ONC–ACBs in this final rule because they would not accomplish our stated objective for surveillance, namely, to confirm that previously certified Complete EHRs and EHR Modules continue to perform "in the field" or in a "live" environment as they did when they were certified.

We believe the term "surveillance" was readily understood by commenters

and is a more appropriate term to use than "monitoring" as suggested by a commenter. As discussed here and noted in the Proposed Rule, we anticipate surveillance will involve the assessment of whether certified Complete EHRs and EHR Modules are continuing to function as intended when they are in operational settings (*i.e.,* "in the field" or in a "live" environment). We noted in the Proposed Rule that if a certified Complete EHR or EHR Module was not functioning in a manner consistent with its certification, we would expect the ONC–ACB to identify the reason(s) the Complete EHR or EHR Module was not functioning properly. We expect surveillance results will indicate the reason(s) behind a Complete EHR or EHR Module's failure to function properly, such as an implementation error, a misapplication by a user, or other factors.

To further illustrate our expectations for surveillance, we offer the following examples based on the capabilities included in three certification criteria. When ONC–ACBs perform surveillance, we would expect them to verify that a certified Complete EHR or, if applicable, a certified EHR Module properly performs drug-drug, drug-allergy interaction checks in accordance with § 170.302(a) in an operational setting. This could include, for example, the use of scenarios or test data to determine whether the certified Complete EHR or EHR Module correctly generates automatic notifications of contraindications. If the certified Complete EHR or EHR Module does not correctly generate automatic notifications, we would expect the ONC–ACB to identify the cause of this problem, to the extent that the ONC–ACB is reasonably able to do so. The ONC–ACB might find, for example, that the notifications were turned off by a user or technician, or that the Complete EHR or EHR Module was improperly installed. As a similar example using the capabilities required by §§ 170.304(e)(2) and 170.306(c)(2), a certified Complete EHR or, if applicable, a certified EHR Module must correctly generate (based on the clinical decision support rules it includes) an automatic notification when a scenario or test data would cause such a notification to be triggered. If the certified Complete EHR or EHR Module does not correctly generate an automatic notification, we would expect the ONC–ACB to identify and the surveillance results to reflect the reason(s) why this failed to occur. As a final example, we would expect an ONC–ACB performing surveillance to verify whether a certified Complete EHR or, if applicable, a certified EHR Module correctly generates patient reminder lists as required by § 170.304(d). If patient reminder lists are not correctly generated in an operational setting, then as with the preceding examples, we would expect the ONC–ACB to determine why the patient reminder lists are not being correctly generated to the extent it is reasonably able to do so. We believe these examples should clarify for commenters the extent to which ONC–ACBs will be expected to assess as part of surveillance an end user's use of Certified EHR Technology and the "assembly" of Certified EHR Technology.

We appreciate the broad range of responses and opinions from commenters who suggested possible areas or topics that surveillance could address. As we indicated in the Proposed Rule, we anticipate that we will issue guidance on an annual basis in order to identify specific elements of surveillance that we consider to be a priority. For example, the guidance could specify as a priority specific capabilities required by an adopted certification criterion (*e.g.,* electronic prescribing) or categories of capabilities required by adopted certification criteria (*e.g.* "safety-related" capabilities, which could include computerized provider order entry (CPOE); clinical decision support (CDS); drug-drug, drug-allergy interaction checks; electronic prescribing; and other similar capabilities required by adopted certification criteria). The purpose of this guidance will be to assist ONC–ACBs as they develop their annual surveillance plans by providing them with information on topics that could be addressed in those plans. It will also convey information to other industry stakeholders, such as HIT developers and users, regarding ONC's priorities for surveillance. We presume that this guidance could include topics that would be consistent from year to year, but that it might also include specific focus areas in certain cases, such as when a new certification criterion has been adopted that we believe is important to assess. In developing any future guidance regarding surveillance, we will consider the comments received in the course of this rulemaking, and we expect that the input provided by commenters will prospectively inform our thinking on this topic.

In response to our surveillance proposals, a commenter indicated that Guide 65 does not explicitly call for post-market surveillance. While the words "post-market surveillance" are not expressly included in Guide 65, we interpret Section 13.4 to include this concept when it states that certification bodies "shall periodically evaluate the marked products to confirm that they continue to conform to the standards." With respect to the comment regarding potential revisions to Guide 65, if such revisions were to occur and be finalized, the National Coordinator would evaluate the revised version in the context of the permanent certification program and determine what action to take based on that evaluation.

Comments. Commenters recommended that surveillance be consistent among ONC–ACBs and be conducted using reliable assessment measures that will produce valid and objective results. To ensure consistency, multiple commenters recommended a centralized approach to surveillance with one commenter recommending that the ONC–AA be responsible for ensuring a consistent approach to surveillance among the ONC–ACBs it accredits. Commenters suggested various methods for conducting surveillance, but generally agreed that the methods should meet scientific and industry best practices regarding sampling, statistical significance, independence and transparency of evaluation. One commenter suggested conducting surveys of Complete EHR and EHR Module purchasers. Another commenter recommended that surveillance be conducted through actual inspection and/or testing, rather than through a passive form of review. Some commenters contended that surveillance must be conducted at more than one individual site to ensure a statistically valid sample. To obtain a valid sample, commenters recommended using a representative sample, such as a percentage of a Complete EHR or EHR Module developer's customer base or an assessment based on no less than five customer sites. A few commenters suggested that intervals of surveillance be clearly specified.

Response. Although we stated in the Proposed Rule that ONC–ACBs should have flexibility in developing their approaches to surveillance, we strongly agree with the commenters that there should be consistency among these surveillance approaches and that surveillance should be conducted through methods that meet scientific and industry best practices regarding sampling, statistical significance, independence and transparency of evaluation. To achieve a necessary degree of consistency, we believe and agree with the commenter who suggested that the ONC–AA should be responsible for ensuring that all of the certification bodies it accredits will use

similar and comparable surveillance approaches. Therefore, we are revising proposed paragraph (b)(2) of § 170.503 to require an accreditation organization that seeks to become the ONC–AA to submit a detailed description of how its accreditation requirements will ensure that the surveillance approaches employed by ONC–ACBs will include the use of consistent, objective, valid, and reliable methods. We are also revising paragraph (e)(2) of § 170.503 to state that an ONC–AA must, in accrediting certification bodies, not only verify conformance to, at minimum, Guide 65, but also ensure that the surveillance approaches across all of the certification bodies that it accredits include the use of consistent, objective, valid, and reliable methods. We believe that these parameters will still provide sufficient flexibility for ONC–ACBs to develop their surveillance plans and conduct surveillance, but also meet our programmatic goals and addresses concerns expressed by commenters, such as ensuring that the sampling mechanisms used by ONC–ACBs are appropriate and that one ONC–ACB will not use appreciably more stringent surveillance methods than another ONC–ACB.

Comments. A few commenters recommended that we should conduct and make publicly available a study and/or analysis to evaluate the options for surveillance, provide specific proposals for surveillance based on the results, and obtain feedback from stakeholders through a process of public notice and comment. Similarly, commenters asserted that if the National Coordinator intends to specify the elements of surveillance that will be required as part of ONC–ACBs' surveillance plans, then the public should have an opportunity to comment on the specific elements. A commenter requested that before ONC–ACBs are instructed to conduct surveillance, ONC should provide additional information and an opportunity for the industry to comment on ONC's positions, particularly with respect to various questions raised by the commenter. One commenter suggested that all ONC–ACB surveillance plans should be subject to review and public comment to allow input from technology vendors.

Response. We do not believe it is necessary at this time to conduct a study or analysis of potential approaches to surveillance because, as explained above, we have provided an approach to surveillance that we believe is appropriate for the permanent certification program. We did not intend to imply as some commenters may have interpreted that there would be a formal opportunity for the public to comment on the surveillance plans that will be submitted by ONC–ACBs or ONC's recommendations on specific elements that could be addressed in those plans. In order to apply for ONC–ACB status, a certification body first must develop its surveillance approach in accordance with Guide 65 and then seek accreditation by the ONC–AA. The ONC–AA in turn will subsequently evaluate whether the certification body's proposed approach to surveillance is consistent with Guide 65 in general and more specifically with section 13 that addresses the concept of surveillance. As we explained in the Proposed Rule, Guide 65 constitutes a minimum threshold that certification bodies will need to meet in order to become accredited, and as such, the ONC–AA could specify additional requirements for surveillance as part of its program to accredit certification bodies. With respect to the annual surveillance plans submitted to the National Coordinator, we expect that these plans will be based on and consistent with the requirements of an ONC–ACB's accreditation. As we mentioned in the Proposed Rule and further discussed above, we expect to issue annual guidance to ONC–ACBs to inform their understanding of topics or elements that may be addressed in the surveillance plans. As we develop that guidance, we will take into account the comments discussed above and may seek additional input from the public if necessary, such as through the HIT Policy Committee.

Comments. Commenters suggested that surveillance should include the input of eligible professionals and eligible hospitals. These commenters suggested that efficient feedback could be achieved either through a feedback process incorporated into Certified EHR Technology or by requiring a "label" on Complete EHRs and EHR Modules that provides instructions for reporting complaints or concerns. One commenter suggested such a "complaint process" could be patterned after the Council for Affordable Quality Healthcare (CAQH's) Committee on Operating Rules for Information Exchange (CORE) policies and processes for documenting and correcting compliance violations. A commenter also stated that, to ensure objectivity and eliminate bias, Complete EHR and EHR Module developers should be prevented from influencing evaluations.

Commenters suggested that the publication of surveillance results would be a beneficial tool for eligible professionals and eligible hospitals seeking to purchase Certified EHR Technology in an effort to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs. Commenters expressed opinions, however, that Complete EHR and EHR Module developers should have an opportunity to respond to "negative input" before surveillance results are published and that surveillance results should not be used to influence specific purchasing decisions because this might implicate a conflict of interest in the role of an ONC–ACB.

Response. In general, eligible professionals and eligible hospitals should have the opportunity to provide feedback through a complaints process established by Complete EHR and EHR Module developers. Guide 65, Section 15 instructs an ONC–ACB to ensure that the developers of the HIT that it certifies have a process in place for receiving and addressing complaints related to certified products. Section 15 also requires that the HIT developers make complaint records available to the ONC–ACB upon request. We anticipate that eligible professionals and eligible hospitals may also have the opportunity to provide feedback about the capabilities of the Complete EHRs and EHR Modules that they possess in those cases where they are contacted by an ONC–ACB to participate in surveillance.

Because an ONC–ACB's accreditation and credibility is at stake with respect to the certifications it issues, we believe it will take the proper steps to prevent EHR technology developers from inappropriately influencing the outcomes of surveillance. However, we also expect that through the procedures developed by ONC–ACBs for performing surveillance, Complete EHR and EHR Module developers will be provided an opportunity to give input to an ONC–ACB, where appropriate, regarding the surveillance results obtained by the ONC–ACB prior to it reporting such results to the National Coordinator. Therefore, we do not expect it will be necessary to provide for any additional opportunity for input from Complete EHR and EHR Module developers after surveillance results have been submitted by an ONC–ACB to the National Coordinator. Lastly, although we indicated in the Proposed Rule that we expected to make the surveillance results that we receive from ONC–ACBs publicly available, we have not yet determined whether or in what form these results will be made available.

Comments. We received comments both supporting and opposing the option for the National Coordinator to take proactive steps to protect purchasers of certified technology (for

example, by "decertifying" the technology) if a pattern of unsatisfactory surveillance results emerges and an ONC–ACB has not taken any measures to evaluate the poor performance. Commenters expressed support for the idea of "decertification" if a pattern of unsatisfactory surveillance results emerged because it is important to protect purchasers of Complete EHRs and/or EHRs Modules. Alternatively, a commenter suggested that if the ONC–ACB in question does not take any measures to evaluate the poor performance of a certified Complete EHR or EHR Module, then the National Coordinator should have another ONC–ACB conduct the evaluation or the National Coordinator should conduct the evaluation before proceeding with decertification. Some commenters stated that any form of decertification should be left to the discretion of the ONC–ACBs. Other commenters asked us to explain how a decertification process would be conducted and to provide an opportunity for the public to comment on the process. Multiple commenters recommended that we should consider the impact decertification would have on eligible professionals and eligible hospitals that are using the affected certified Complete EHR or EHR Module to meet the requirements of the Medicare and Medicaid EHR Incentive Programs.

Response. We appreciate the thoughtful comments that were submitted on this matter, although we will not use this final rule to establish a process for the decertification of Complete EHRs and/or EHR Modules. After ONC–ACBs begin to conduct surveillance and submit the results to the National Coordinator, we will have an opportunity to assess the results and determine whether ONC–ACBs are taking appropriate action to address any patterns of unsatisfactory results. If we determine that unsatisfactory surveillance results are not being addressed, or if the results indicate certified Complete EHRs or EHR Modules are adversely affecting public health or safety or the programmatic goals of the permanent certification program, we will consider what steps are necessary to respond to the particular situation at issue at that time. In taking any action, commenters can be assured that the National Coordinator will consider the impact on eligible professionals and eligible hospitals who are using certified products to meet the requirements of the Medicare and Medicaid EHR Incentive Programs. We believe the potential consequences of failing to fulfill their responsibilities, such as facing corrective action under the permanent certification program or losing reputational standing and business in the market, will sufficiently motivate the ONC–AA and the ONC–ACBs to take the necessary actions to ensure surveillance plans are followed and unsatisfactory surveillance results are properly addressed. We also believe that the potential for surveillance results to be made publicly available as we proposed will sufficiently motivate developers of Complete EHRs and/or EHR Modules to improve their products and address any shortcomings identified by the ONC–ACB surveillance process.

g. Refunds

We proposed in § 170.523(j) to require an ONC–ACB to promptly refund any and all fees received for certifications that will not be completed.

Comments. Commenters requested that we clarify that refunds would only be required where an ONC–ACB's conduct caused the certification to be incomplete as opposed to the failure of a developer of Complete EHRs, EHR Modules and/or other types of HIT to meet certification requirements. One commenter contended that this provision should only apply when an ONC–ACB has its accreditation status revoked. Another commenter suggested that our proposed requirement for ONC–ACBs to return funds should also apply to situations where developers are required to recertify their products because of misconduct by an ONC–ACB.

Response. We agree with the commenters that suggested our proposed refund requirement needs clarification. As advocated by the commenters and as clarified for ONC–ATCBs in the Temporary Certification Program final rule, it was our intention to require ONC–ACBs to issue refunds only in situations where an ONC–ACB's conduct caused certification to not be completed. We also agree with the one commenter that this would include situations where a Complete EHR and/or EHR Module is required to be recertified because of the conduct of an ONC–ACB. Similarly, if an ONC–ACB were to be suspended by the National Coordinator under the suspension provisions we have incorporated in this final rule, an ONC–ACB would be required to refund all fees paid for certification if a Complete EHR or EHR Module developer withdraws a request for certification while the ONC–ACB is under suspension.

We are revising § 170.523(j) consistent with our discussion above.

h. Suggested New Principles of Proper Conduct

We received a few comments that suggested we should adopt additional principles of proper conduct. These comments concerned the impartiality and business practices of ONC–ACBs.

Comments. A commenter recommended that applicants for ONC–ACB status should be required not to have an interest, stake and/or conflict of interest in more than one entity receiving ONC–ACB status nor have any conflict of interest with EHR product companies actively promoting EHR products in the marketplace. Another commenter recommended that we adopt a principle of proper conduct that requires an ONC–ACB to establish, publish and adhere to a non-discriminatory protocol to ensure that requests for certification are processed in a timely manner beginning on the date the ONC–ACB sets for accepting requests for certification. One commenter recommended that all requests for certification be required to be processed within 6 months of receipt by an ONC–ACB.

Response. Applicants for ONC–ACB status and ONC–ACBs must be accredited, which requires adherence to the requirements of Guide 65 at a minimum. These requirements explicitly obligate certification bodies to conduct business in an impartial manner. For instance, an applicant for ONC–ACB status and/or an ONC–ACB must have a documented structure which safeguards impartiality, including provisions to ensure the impartiality of the operations of the certification body and that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its certifications. Guide 65 also specifically states that "access shall not be conditional upon the size of the [Complete EHR or EHR Module developer] or membership [in] any association or group, nor shall certification be conditional upon the number of certificates already issued." We believe these provisions as well as other impartiality provisions contained in Guide 65 will adequately address any potential conflicts of interest, potential discriminatory practices, or other situations that might jeopardize the integrity of the permanent certification program. We will not require requests for certification to be completed within six months as the commenter proposed. A predetermined timeframe is not realistic because the time it takes for a product to be certified will likely vary based on factors such as the current number of ONC–ACBs, the volume of

requests for certification, the type of product that is submitted for certification, and an ONC–ACB's specific business practices.

3. Application Submission

We proposed in § 170.525 to allow an applicant for ONC–ACB status to submit its application either electronically via e-mail (or web submission if available), or by regular or express mail at any time during the existence of the permanent certification program. We did not receive any comments on this proposal. We are, however, revising § 170.525 to clarify that an applicant for ONC–ACB status may submit its application at any time after the permanent certification program has been established by this final rule.

4. Overall Application Process

We received a few comments regarding the overall application process.

Comment. One commenter contended that there is an optimal number of ONC–ACBs that can effectively perform certification in both the near and long term. The commenter reasoned that if there are too few ONC–ACBs, then the ONC–ACBs will be unable to handle the demand for certifications that can be expected at the outset of the permanent certification program. Alternatively, the commenter reasoned that if there are too many ACBs, the demand for their services may not be sufficient for all of them to remain financially viable. The commenter believed the key to the appropriate number of ONC–ACBs is for ONC to determine the ONC–ACBs' ability to handle the needs of the market. Another commenter suggested that the number of ONC–ACBs be limited to 5. The commenter reasoned that there might be variances in certification processes if there are too many ONC–ACBs, while limiting the number of ONC–ACBs to 5 organizations will ensure that an ONC–AA will be able to effectively monitor the ONC–ACBs. One commenter suggested that applicants for ONC–ACB status preferably be not-for-profit organizations.

Response. We believe it is appropriate to allow all qualified applicants to apply and obtain ONC–ACB status and that organizations will determine whether pursuing ONC–ACB status can be a successful business venture. We believe that a greater number of successful applicants for ONC–ACB status will benefit the market in terms of increased competition and more options for the certification of Complete EHRs, EHR Modules, and/or other types of HIT. Restricting the number of ONC–ACBs or imposing arbitrary eligibility requirements on applicants, such as requiring an applicant to be a not-for-profit organization, will only limit these potential benefits. Further, we believe that the requirements of the permanent certification program, including requiring accreditation from a sole ONC–AA and adherence to the Principles of Proper Conduct for ONC–ACBs, will ensure the necessary consistency in certifications granted by ONC–ACBs.

Comments. A commenter recommended that we provide for "provisional acceptance" of an organization before requiring an organization to go through full accreditation to become an ONC–ACB. The commenter believed this would lessen the risk for organizations in pursuing ONC–ACB status.

Response. Based on the structure of the permanent certification program and the important role played by the ONC–AA, we do not believe that we could properly evaluate the qualifications of an organization until after it had obtained the appropriate accreditation. Therefore, we do not believe we could offer any form of "provisional acceptance" without fundamentally altering the permanent certification program's structure.

H. ONC–ACB Application Review, Reconsideration, and ONC–ACB Status

In the Proposed Rule, we proposed to review an application for ONC–ACB status and issue a decision within 30 days in most cases. We proposed that if an applicant was issued a denial notice and certain criteria were met, an applicant could seek reconsideration of the denied application. We proposed that if an applicant's application were deemed satisfactory, we would make it publicly known that the applicant had achieved ONC–ACB status and that the ONC–ACB would be able to begin certifying consistent with the authorization granted by the National Coordinator. We further proposed that an ONC–ACB's status would expire two years from the date it was granted unless it was renewed.

1. Application Review

We proposed in § 170.530 that we would review completed applications in the order in which we received them and that the National Coordinator would issue a decision within 30 days of receipt of an application submitted for the first time.

We proposed that the National Coordinator would be able to request clarification of statements and the correction of inadvertent errors or minor omissions. In these cases, before issuing a formal deficiency notice, we proposed that the National Coordinator may request such information from the applicant's authorized representative as an addendum to its application. We further proposed that if the applicant failed to provide such information to the National Coordinator within the timeframe specified, which would not be less than 5 days, the National Coordinator could issue a formal deficiency notice. In other circumstances, the National Coordinator could immediately send a formal deficiency notice if it was determined that significant deficiencies existed which could not be addressed by a clarification or correction of a minor omission.

We proposed that the National Coordinator would identify any deficiencies in an application and provide an applicant with an opportunity to correct any deficiencies by submitting a revised application in response to a deficiency notice. We proposed that an applicant would have 15 days to submit a revised application in response to a deficiency notice and that the National Coordinator would be permitted up to 15 days to review a revised application once it has been received. We further proposed that if the National Coordinator determined that a revised application still contained deficiencies, the applicant would be issued a denial notice indicating that the applicant would no longer be considered for authorization under the permanent certification program.

We proposed that an applicant could request reconsideration of the decision in accordance with § 170.535. We proposed that an application would be deemed satisfactory if it met all of the application requirements. We further proposed that once the applicant was notified of this determination, the applicant would be able to represent itself as an ONC–ACB and begin certifying Complete EHRs, EHR Modules and/or other types of HIT consistent with its authorization.

Comments. We did not receive any comments specific to § 170.530. We did, however, receive two comments on the temporary certification program application review provisions during the permanent certification program public comment period that are equally applicable to § 170.530. A commenter expressed agreement and support for the proposed process affording the National Coordinator discretion to request clarifications of statements or corrections of errors or omissions, but the commenter did not agree that such requests should be limited to only

inadvertent or minor errors. The commenter reasoned that given the time constraints and complexity of the application process, the National Coordinator should be able to consider requesting clarifications or corrections in a collaborative process with applicants, as appropriate. The commenter also expressed general agreement with our proposal that an applicant be provided up to 15 days to respond to a formal deficiency notice. The commenter suggested, however, that considering our position that not many organizations will be capable of obtaining authorization under the certification programs, the National Coordinator should have the discretion to grant an extension beyond the 15-day response period upon a showing of good cause by the applicant.

Response. Based on the comments received, we believe that certain modifications to the ONC–ACB application review process would be beneficial for ONC–ACB applicants as well as the permanent certification program as a whole. We made similar modifications to the ONC–ATCB application review process in the Temporary Certification Program final rule.

We agree with the commenter that the process for the National Coordinator to seek corrections of errors and omissions should be revised. Therefore, as recommended by the commenter, we are removing the words "inadvertent" and "minor" from § 170.530(b)(1). Although we anticipate that the National Coordinator would likely seek correction of only minor errors or omissions (*e.g.,* missing contact information of an authorized representative as opposed to a more significant deficiency such as not providing sufficient documentation that confirms that the applicant has been accredited by the ONC–AA), these revisions will provide the National Coordinator with more flexibility to allow an applicant to correct an error or omission instead of issuing a deficiency notice to the applicant. This flexibility will be beneficial for applicants and the permanent certification program itself considering the limited opportunities and short timeframes for correcting applications. Similarly, we believe that the application review process would be improved if the National Coordinator could also request the clarification of statements and the correction of errors or omissions in a revised application. This change will make the application review process more collaborative as suggested by the commenter. Therefore, we are also revising § 170.530 to allow the National Coordinator to request clarification of statements and the correction of errors or omissions during the 15-day period provided for review of a revised application.

We are making additional revisions to § 170.530 in response to the commenter's recommendation that the National Coordinator should have the discretion, upon a showing of good cause by the applicant, to grant an extension beyond 15 days for an applicant to submit a revised application in response to a deficiency notice. We agree with the commenter's recommendation and are revising § 170.530 to allow an applicant for ONC–ACB status to request an extension of the 15-day period for submitting a revised application in response to a deficiency notice and to provide the National Coordinator with the option of granting an applicant's request for additional time to respond to a deficiency notice upon a showing of good cause by the applicant. In determining whether good cause exists, the National Coordinator will consider factors such as: change in ownership or control of the applicant organization; the unexpected loss of a key member of the applicant's personnel; damage to or loss of use of the applicant's facilities, working environment or other resources; or other relevant factors that would prevent the applicant from submitting a timely response to a deficiency notice.

We believe it is unnecessary to establish a predetermined period of time for a good cause extension. Instead, the duration of an extension will be determined based on an applicant's particular circumstances that constitute good cause for the extension. For example, if an applicant is accredited but fails to submit sufficient documentation of its accreditation, a good cause extension could be granted for a period of time that would allow the applicant to obtain and submit the appropriate documentation.

We proposed in § 170.530(c)(4) that if the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant will no longer be considered for authorization under the permanent certification program. We believe this section should be modified in order to allow unsuccessful applicants to reapply for ONC–ACB status after a period of time has passed. Although we proposed in § 170.535 that applicants could submit a request for the National Coordinator to reconsider a denial notice, this reconsideration process is only applicable to an application that is the subject of a denial notice and only in limited circumstances. We believe revisions to § 170.530(c)(4) are necessary because, as discussed below, it could significantly compromise the quality of the permanent certification program if qualified applicants are unable to reapply for ONC–ACB status because they were previously issued a denial notice. Consequently, we are revising this section to state that a denial notice will indicate that the applicant cannot reapply for ONC–ACB status for a period of six months from the date of the denial notice.

As proposed, § 170.530(c)(4) would prevent applicants from reapplying and being considered for ONC–ACB status if they have been issued a denial notice for the permanent certification program. Once a denial notice has been issued, the unsuccessful applicant would be permanently barred from submitting any subsequent applications for ONC–ACB status. We believe that a permanent bar on reapplying for ONC–ACB status could potentially have detrimental effects on the permanent certification program. Unlike the temporary certification program, the permanent certification program has no anticipated sunset date and is expected to continue indefinitely. We believe an applicant for ONC–ACB status that receives a denial notice should be given an opportunity to correct the deficiency or deficiencies on which the denial notice was based. For example, an applicant that is otherwise qualified to serve as an ONC–ACB could be issued a denial notice if its accreditation is suspended or revoked while its ONC–ACB application is under review. The application review process finalized in this rule is intended to provide applicants with multiple opportunities to correct problems with their applications. We recognize, however, that an applicant may need more time to have its accreditation reinstated than would be possible within the timeframe for application review, even if the applicant could show good cause for an extension. We believe it would be unfair and contrary to the program's best interests not to allow such an applicant to reapply for ONC–ACB status. As another example, an otherwise qualified applicant may be barred from reapplying if it receives a denial notice because it unintentionally missed an established deadline for responding to a deficiency notice and did not request a good cause extension for submitting a revised application. As previously noted, we expect that only a limited number of organizations will possess the requisite qualifications that would enable them to become ONC–

ACBs. Permanently barring qualified applicants from reapplying solely because they had been issued a denial notice would unnecessarily restrict the limited supply of organizations that are qualified to serve as ONC–ACBs. We believe such a restriction would not be in the best interest of the permanent certification program and would undermine our objective to encourage a competitive market for the certification of HIT. Moreover, an applicant that is denied authorization to certify Complete EHRs and/or EHR Modules may still be qualified to certify other types of HIT. We believe such organizations should be given a chance to apply for ONC–ACB status in the event that other types of HIT are included in the permanent certification program after the Secretary adopts applicable certification criteria.

We believe that 6 months is a reasonable period of time for an applicant to wait before it may reapply. By way of comparison, an organization that has had its ONC–ACB status revoked for a Type-1 violation must wait 1 year in accordance with § 170.565(h)(3) before it may reapply for ONC–ACB status. It would be inequitable as well as inconsistent with our program goals to permanently bar an organization from reapplying because it received a denial notice, while allowing an organization that had its ONC–ACB status revoked to reapply after a year. In light of the fact that Type-1 violations include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program, we believe that an organization's inability to meet the application requirements of § 170.520 deserves a far lesser consequence than a permanent bar on reapplying for ONC–ACB status. We believe that a 6-month waiting period will in many cases provide sufficient time for an applicant to evaluate and correct the deficiencies with its application (assuming the deficiencies are capable of correction) and will deter unqualified applicants from repeatedly applying. Accordingly, we are revising paragraph (c)(4) of § 170.530 consistent with the preceding discussion.

We proposed an identical provision in § 170.430(c)(4) for the temporary certification program, which we finalized in the Temporary Certification Program final rule. Under that provision, an applicant that is issued a denial notice cannot reapply and be considered for ONC–ATCB status, which we believe is appropriate for the temporary certification program. We anticipate that the temporary certification program will only remain in existence for a short period of time and expect that it will sunset on December 31, 2011. We expect that a vast majority of certifications will be conducted early in the temporary certification program based on the associated meaningful use requirements and reporting periods of the Medicare and Medicaid EHR Incentive Programs. Further, any applicant that is permanently barred from reapplying for ONC–ATCB status will still be able to apply for ONC–ACB status under the permanent certification program. Therefore, due to the short duration of the temporary certification program and the fact that an unsuccessful applicant for ONC–ATCB status may apply for ONC–ACB status under the permanent certification program, the consequences of a permanent bar on reapplication are not nearly as severe as they would have been under the permanent certification program had we not revised our proposal.

We state in § 170.530(d) that the National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC–ACB status and that once notified, the applicant may represent itself as an ONC–ACB and begin certifying HIT consistent with its authorization. We believe it is important to clarify that there is a distinction between the point at which an organization is notified that it has been granted ONC–ACB status and the point when it may begin to perform certifications consistent with the authorization that it has been granted. To illustrate this distinction with an example, an applicant may be notified in October 2011 that it has been granted ONC–ACB status, although the permanent certification program is not scheduled to begin until at least January 1, 2012. After receiving notice, the ONC–ACB may begin to represent and market itself as ONC–ACB and participate in mandatory ONC training for ONC–ACBs, but its authorization to perform certifications would not become effective until the commencement of the permanent certification program on January 1, 2012 or on a subsequent date when the National Coordinator determines that the permanent certification program is fully constituted. At that time, the ONC–ACB may begin to certify the type(s) of HIT that fall within the scope of its authorization. Similarly, after the ONC–ACB has participated in the permanent certification program for a period of time, it may choose to submit a request to the National Coordinator to expand the current scope of its authorization (for example, to include other types of EHR Modules or Complete EHRs). If the National Coordinator grants its request based on the information it submits and the completion of any applicable mandatory ONC training, then the ONC–ACB's authorization would be expanded effective as of the date specified by the National Coordinator. In both cases (the initial granting of ONC–ACB status and the subsequent expansion of the ONC–ACB's authorization), the National Coordinator would make publicly available the date of the ONC–ACB's authorization and the type(s) of certification included within its authorization, pursuant to § 170.540(a).

2. Application Reconsideration

We proposed in § 170.535 that an applicant after receiving a denial notice may request that the National Coordinator reconsider the denied application only if the applicant can demonstrate that clear, factual errors were made in the review of the application and that their correction could lead to the applicant obtaining ONC–ACB status. We proposed that an applicant would be required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its request for ONC–ACB status and explaining with sufficient documentation what factual errors it believes can account for the denial. We proposed that if the National Coordinator did not receive the applicant's submission within the specified timeframe that its request could be rejected. We proposed that the National Coordinator would have up to 15 days to consider and issue a decision on a timely reconsideration request. We further proposed that if, after reviewing an applicant's reconsideration request, the National Coordinator determined that the applicant did not identify any factual errors or that correction of those factual errors would not remove all identified deficiencies in the application, the National Coordinator could reject the applicant's reconsideration request and that this decision would be final and not subject to further review.

Comments. A commenter expressed agreement with our proposed ONC–ACB application reconsideration process. Another commenter stated, however, that the National Coordinator should have discretion to reconsider an application for reasons besides clear factual errors that could lead to the applicant receiving ONC–ACB status. The commenter suggested that the National Coordinator should consider

several factors in determining whether to reconsider an application, including the severity and type of the deficiency, the implications of the deficiencies, the applicant's level of responsiveness and cooperation, and the remedial efforts taken by the applicant.

Response. We appreciate the one commenter's expression of support for our proposals. We do not agree with the commenter that the National Coordinator should reconsider all applications for any reason. Rather, as we determined for the temporary certification program in the Temporary Certification Program final rule, we believe that the National Coordinator should only reconsider an application if the applicant for ONC–ACB status can demonstrate that there were clear factual errors in the review of its application that could lead to the applicant obtaining ONC–ACB status. We believe that the application requirements and application review processes that we have proposed ensure that only qualified applicants are timely authorized to be ONC–ACBs. The application requirements proposed, particularly the requirement that an applicant be accredited by an ONC–AA, are designed to ensure that applicants are qualified. Our review process is designed to ensure the veracity of an application and to confirm that an applicant has the necessary capabilities to be authorized to conduct the certification sought by the applicant. Our review process is also designed to reach final decisions in a timely manner. Overall, we believe the application review process is efficient yet fair by providing opportunities for the National Coordinator to request clarifications and corrections to the application, opportunities for an applicant to respond to a deficiency notice, and opportunities to request reconsideration of a denial notice if there are clear, factual errors that, if corrected, could lead to the applicant obtaining ONC–ACB status. We also note that if an applicant is unable to demonstrate that clear, factual errors were made in the review of its application, it still would have the ability to reapply for ONC–ACB status after waiting a period of six months. Accordingly, we are finalizing § 170.535 without modification.

3. ONC–ACB Status

We proposed in § 170.540 that the National Coordinator will acknowledge and make publicly available the names of ONC–ACBs, including the date each was authorized and the type(s) of certification each has been authorized to perform. We proposed that each ONC–ACB would be required to prominently and unambiguously identify on its Web site and in all marketing and communications statements (written and oral) the scope of its authorization. We also proposed that an ONC–ACB's status would expire two years from the date it was granted by the National Coordinator unless it was renewed. To renew its status, we proposed that an ONC–ACB submit a renewal request (*i.e.,* an updated application) to the National Coordinator 60 days prior to the expiration of its status.

In association with these proposals, we specifically requested that the public comment on whether there was any additional information an ONC–ACB should provide the National Coordinator in order to have its status renewed, such as documentation of the ONC–ACB's current accreditation status and any additional information or updates to the original application that would aid in the National Coordinator's review of the renewal request.

Comments. A commenter expressed an opinion that it is important to the industry that the National Coordinator makes distinctions as to what a certifying body is authorized to certify. One commenter recommended that our requirements related to marketing and communications be limited to the ONC–ACB's Web site and all marketing and communications pertaining to its role in the certification of Complete EHRs, EHR Modules and/or other types of HIT under the permanent certification program. As currently written, the commenter contended that the requirements apply to all marketing and communications made by the entity even if unrelated to their ONC–ACB status.

Commenters expressed agreement with having an ONC–ACB's status expire after two years, while others suggested 3-year and 4-year terms. The commenters requesting longer terms stated that a longer term would promote more stability and lessen overhead costs for ONC–ACBs. A commenter that suggested a 3-year term reasoned that a 3-year term could run concurrent with the ONC–AA's term. The commenter also requested that in cases where the ONC–AA has its status revoked or not renewed, ONC–ACBs should be allowed to retain their status with ONC until at least 12 months after a new ONC–AA has been appointed by ONC. The commenter reasoned that this would allow time for "reaccreditation" by the approved accreditation organization.

In terms of what information we should consider for the renewal of an ONC–ACB's status, commenters generally agreed that an ONC–ACB should provide updated accreditation information and demonstrate compliance with the Principles of Proper Conduct for ONC–ACBs. Commenters also suggested that ONC request and consider Complete EHR and EHR Module developers' evaluations of ONC–ACBs' performance, documentation regarding the handling of customer complaints by ONC–ACBs, the percentage of certifications in relation to requests for certification, the total number of previous certifications granted, the number of certifications granted after two or more attempts, and surveillance results.

Response. We appreciate the support for our proposals and reiterate that, as proposed, an ONC–ACB will only be able to certify Complete EHRs, EHR Modules and/or other types of HIT consistent with the scope of authorization granted by the National Coordinator. Additionally, as proposed, the ONC–ACB will have to prominently and unambiguously display the scope of authorization granted to it by the National Coordinator. To address the commenter's concern about the overreach of our proposed requirement that an ONC–ACB "identify on its Web site and in all marketing and communications statements (written and oral) the scope of its authorization" we have clarified the language to clearly state that the requirement only applies to activities conducted by the ONC–ACB under the permanent certification program. Specifically, we have revised the provision to state, in relevant part, "each ONC–ACB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program."

We believe, after consideration of public comments, that an ONC–ACB should be allowed to maintain its status for three years, instead of the proposed two years, from the date it is granted before being required to renew its status. Considering that an applicant could obtain ONC–ACB status at any time during the permanent certification program, it would be impossible to align the tenure of the ONC–AA with that of the ONC–ACBs. However, a three-year term for ONC–ACBs will offer additional stability for those HIT developers seeking certification under the permanent certification program as well as for ONC–ACBs. It will also lessen the reapplication burden for ONC–ACBs. We anticipate by beginning the process to approve an ONC–AA at least 180 days prior to the end of the then-current ONC–AA's term, there will

be minimal disruption in the accreditation processes if we were to select a different ONC–AA. As previously noted in this final rule, we intend to issue an NPRM that will address improper conduct by an ONC–AA and propose a corrective action process. At that time, we will consider the implications for ONC–ACBs if an ONC–AA's status is revoked or other corrective action is taken.

We do not believe that there is a need to require an ONC–ACB to provide any of the information suggested by the commenters for ONC to consider in determining whether to renew an ONC–ACB's status. The Principles of Proper Conduct for ONC–ACBs require an ONC–ACB to submit a weekly list of certified Complete EHRs, EHR Modules, and/or other types of HIT, attend mandatory training, and submit an annual surveillance plan and annually report surveillance results. Accreditation requires an ONC–ACB to be compliant with Guide 65 at a minimum, which requires an ONC–ACB to have a complaints process that includes documentation of the resolution of complaints. Accreditation also involves a regular review of an ONC–ACB's processes and performance. Consequently, we believe that by maintaining its accreditation and adhering to the Principles of Proper Conduct for ONC–ACBs, an ONC–ACB will be more than adequately situated to pursue renewal.

To renew its status, an ONC–ACB must submit to the National Coordinator the information specified in § 170.520(a) and (c) that would otherwise be required to apply for ONC–ACB status and, if applicable, include any requests to expand the current scope of its authorization. We expect that an ONC–ACB will be providing updates to the information specified in § 170.520(b) as part of its compliance with the Principles of Proper Conduct for ONC–ACBs. Therefore, we do not expect an ONC–ACB to submit its "general identifying information" unless the information that is on record with ONC is outdated or otherwise incorrect. Lastly, we do not believe it will be necessary for an ONC–ACB to execute and submit a new agreement to adhere to the Principles of Proper Conduct for ONC–ACBs because the initial agreement that was executed when the organization obtained ONC–ACB status will remain valid as long as the organization maintains its ONC–ACB status.

We are revising § 170.540 consistent with this discussion, including clarifying the representation requirements of ONC–ACBs, extending the term of ONC–ACB status to 3 years and clarifying that a renewal request must include any updates to the information specified in § 170.520.

I. Certification of Complete EHRs, EHR Modules and Other Types of HIT

In the Proposed Rule, we described the scope of authority that would be granted to certification bodies that become ONC–ACBs. We also specified which certification criterion or criteria ONC–ACBs would be required to use to certify Complete EHRs, EHR Modules and/or other types of HIT. As discussed below, the comments we received on these proposed provisions were in many cases also applicable to analogous provisions of the temporary certification program. As a result of the similarities that exist between the temporary and permanent certification programs, our responses to the comments below are often similar or identical to responses we provided in the Temporary Certification Program final rule.

1. Complete EHRs

We proposed in § 170.545 that to be authorized to certify Complete EHRs under the permanent certification program, an ONC–ACB would need to be capable of certifying Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of part 170. We further proposed that an ONC–ACB that had been authorized to certify Complete EHRs would also be authorized to certify all EHR Modules under the permanent certification program.

Comments. Commenters expressed agreement with our proposals that, in order to be authorized to certify Complete EHRs under the permanent certification program, an ONC–ACB must be capable of certifying Complete EHRs to all applicable certification criteria and that such an ONC–ACB would also be authorized to certify all EHR Modules under the permanent certification program. One commenter recommended that we *require* ONC–ACBs authorized to certify Complete EHRs to also certify EHR Modules.

Response. We appreciate the commenters' support for our proposals, but we do not adopt the one commenter's recommendation that we require an ONC–ACB that is authorized to certify Complete EHRs to also certify EHR Modules. We clearly acknowledged in the preamble of the Proposed Rule and in our proposed regulatory provision that an ONC–ACB authorized to certify Complete EHRs would also have the capability and, more importantly, the authorization from the National Coordinator to certify EHR Modules. We do not, however, believe that we should require an ONC–ACB that is authorized to certify Complete EHRs to also certify EHR Modules. An ONC–ACB, despite its authorization to do so, might have multiple business justifications for choosing not to certify EHR Modules, such as an insufficient number of qualified employees to conduct the certification of EHR Modules in addition to conducting certification of Complete EHRs, or that doing both would not be as profitable a business model.

Based on consideration of the comments received and review of the proposed provision, we are revising § 170.545(a) to state that "When certifying Complete EHRs, an ONC–ACB must certify Complete EHRs in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part." This revision is consistent with our description of certification of Complete EHRs in the Proposed Rule preamble, as well as the approach we finalized for the temporary certification program. It also makes explicit that ONC–ACBs must not only be capable, but as with EHR Modules, are required to certify Complete EHRs to all of the applicable certification criteria adopted by the Secretary under subpart C of part 170. We are also redesignating proposed paragraph (b) as paragraph (e) because of additional revisions we are making to § 170.545. These revisions are discussed in sections *F. Certification Options for ONC–ACBs, O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status* and *P. Differential or Gap Certification* of this preamble.

2. EHR Modules

a. Applicable Certification Criterion or Criteria

We proposed in § 170.550(a) and (b) that an ONC–ACB must certify EHR Modules in accordance with the applicable certification criterion or criteria adopted by the Secretary at subpart C of part 170. In the preamble of the Proposed Rule, we clarified that a single certification criterion would encompass all of the specific capabilities referenced below the first paragraph level. For example, 45 CFR 170.302, paragraph "(f)" (the first paragraph level) identifies that this certification criterion relates to recording and charting vital signs. It includes three specific capabilities at (f)(1), (2), and (3) (the second paragraph level): the ability to record, modify, and retrieve patients' vital signs; the ability to calculate body mass index (BMI); and

the ability to plot and display growth charts. We stated that we viewed the entire set of specific capabilities required by paragraph "(f)" (namely, (f)(1), (2), and (3)) as one certification criterion. The specific capability to calculate BMI, for example, would not be equivalent to one certification criterion.

Comments. We received two comments on our proposal. One commenter expressed agreement with our proposal, including the appropriateness of requiring an EHR Module to be capable of performing all the functions specified at the paragraph level of a certification criterion. The commenter reasoned that to allow certification at a lower level (subparagraph) would result in a very large number of EHR Modules that would overcomplicate the certification program. The commenter stated that the only exception might be if there were a very large number of subparagraphs within a criterion or a very large number of criteria within a single objective. In that case, the commenter asserted that the EHR Module might be divided into two or more logically related groups. But in general, the commenter stated that having a range of 20–25 certification criteria, and therefore potential EHR Modules, was an appropriate level of granularity.

The other commenter stated that requiring an EHR Module to perform all of the listed functions or capabilities associated with a specific certification criterion would create a problem. In particular, the commenter stated that for the "drug-drug, drug-allergy, drug-formulary checks" certification criterion specified in the HIT Standards and Certification Criteria interim final rule, there did not appear to be a single EHR Module in the current HIT marketplace that performs all of the four listed capabilities under the criterion. Therefore, the commenter recommended that we narrow the scope of EHR Module certification to one of the capabilities or functions (subparagraphs) of a criterion. The commenter stated that this solution would necessitate that the ONC–ACB provide EHR Modules that only perform such discrete functions with a "conditional certification" that carries the caveat that the EHR Module must be used in conjunction with other certified EHR Modules to offer full and complete functionality for the applicable criterion.

Response. We agree with the first commenter that, as proposed, EHR Modules should be certified to the first paragraph level of a certification criterion, as described in our example above. We believe that this is the most appropriate level for certification of EHR Modules because, in most cases, this level of a criterion most fully represents the capabilities that are needed to perform the associated meaningful use objectives. We addressed the concern expressed by the other commenter about the "drug-drug, drug-allergy, drug-formulary checks" certification criterion by adopting separate certification criteria in the HIT Standards and Certification Criteria final rule.

We are modifying § 170.550 to remove proposed paragraph (b) because it is repetitive of the requirements set forth in paragraph (a). We made a similar modification to § 170.450 in the Temporary Certification Program final rule.

b. Privacy and Security Certification

With respect to EHR Modules, we discussed in the Proposed Rule when ONC–ACBs would be required to certify EHR Modules to the privacy and security certification criteria adopted by the Secretary. We proposed in § 170.550(c) that EHR Modules must be certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for certification in one of the following manners:

- The EHR Module(s) are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which could otherwise constitute a Complete EHR. In such instances, the EHR Module(s) shall be certified in the same manner as a Complete EHR. Pre-coordinated, integrated bundles of EHR Module(s) which include EHR Module(s) that would not be part of a local system and under the end user's direct control are excluded from this exception. The constituent EHR Modules of such a pre-coordinated, integrated bundle must be separately certified to all privacy and security certification criteria;
- An EHR Module is presented for certification, and the presenter can demonstrate to the ONC–ACB that it would be technically infeasible for the EHR Module to be certified in accordance with some or all of the privacy and security certification criteria; or
- An EHR Module is presented for certification, and the presenter can demonstrate to the ONC–ACB that the EHR Module is designed to perform a specific privacy and security capability. In such instances, the EHR Module may only be certified in accordance with the applicable privacy and security certification criterion/criteria.

Comments. A number of commenters supported our proposed approach and agreed that EHR Modules should be certified to all adopted privacy and security certification criteria unless there were justifiable reasons for which they should not. Other commenters suggested changes to one or more of the stated exceptions and posed questions for our consideration. Some commenters recommended that we deem certification criteria "addressable" similar to the Health Insurance Portability and Accountability Act (HIPAA) Security Rule's application of the word "addressable" to certain implementation specifications (in the HIPAA context) within a security standard (in the HIPAA context). Other commenters noted that with respect to the second exception, involving the demonstration that it would be technically infeasible for an EHR Module to be certified to some or all privacy and security certification criteria, that the term "inapplicable" should be added as a condition in addition to "technically infeasible." Another commenter stated that we should remove the third exception, involving the demonstration that an EHR Module is designed to perform a specific privacy and security capability, because, depending on how the privacy and security EHR Module is developed, it may also need to include certain capabilities, such as an audit log.

One commenter noted that, under the permanent certification program, an EHR Module developer would first be required to demonstrate to a testing laboratory that it is technically infeasible to certify an EHR Module to a particular privacy and security certification criterion, which would require the testing laboratory to make an independent subjective decision on technical feasibility. The commenter recommended that ONC and/or NIST develop an "applicability matrix" to reduce subjectivity and ensure consistent determinations among testing laboratories and ONC–ACBs related to the applicability of privacy and security certification criteria to EHR Modules. Another commenter expressed an understanding of our privacy and security certification approach to EHR Modules, but cautioned that to ensure the privacy and security of an EHR system in its entirety, that the entire combination needs to be tested for privacy and security due to variances that can occur in how EHR Modules perform once they are "linked." The commenter suggested that an EHR Module developer should be required to

explain how the EHR Module will be "securely" assembled.

Response. We appreciate commenters' support for our proposed approach and the thoughtfulness of the responses. While we understand and appreciate the similarities some commenters saw with respect to the HIPAA Security Rule and leveraging the "addressable" concept, we do not believe that making each privacy and security certification criterion "addressable" in the way it is implemented under the HIPAA Security Rule is an appropriate approach for the purposes of certifying EHR Modules.

In the context of the HIPAA Security Rule, HIPAA covered entities must assess whether each addressable implementation specification (in the HIPAA Security Rule) is a reasonable and appropriate safeguard in its environment. If a HIPAA covered entity determines that an addressable implementation specification is reasonable and appropriate, then the covered entity is required to implement it. If a HIPAA covered entity determines that an addressable implementation specification is not reasonable and appropriate, the covered entity is required to: (1) document why it would not be reasonable and appropriate to implement the addressable implementation specification; and (2) implement an equivalent alternative measure if reasonable and appropriate. While this is a sensible approach for HIPAA covered entities, we do not believe that it translates well into the certification of EHR Modules.

All HIPAA covered entities are required to comply with the HIPAA Security Rule with respect to their electronic protected health information, regardless of their size and resources. Accordingly, the HIPAA Security Rule provides for a flexible approach, allowing a HIPAA covered entity to implement safeguards that are reasonable and appropriate for its unique environment. We do not believe that this approach is appropriate for certifying EHR Modules because one purpose of certification is to assure eligible professionals and eligible hospitals that an EHR Module includes a specified capability or set of capabilities. For these reasons and as we concluded in the Temporary Certification Program final rule, we believe that the proposed standard of "technically infeasible" is more appropriate than the HIPAA Security Rule's "addressable" concept for the purposes of certifying EHR Modules. Thus, an EHR Module developer must satisfy each privacy and security criterion where it is technically feasible.

To complement our "technically infeasible" standard, we agree with those commenters that recommended the addition of the word "inapplicable" to the second proposed exception. We believe that in some cases a privacy and security certification criterion may be inapplicable to an EHR Module while technically feasible to implement, and in other cases a privacy and security certification criterion may be applicable but technically infeasible to implement. For example, it may be technically feasible to implement an automatic log-off or emergency access capability for several types of EHR Modules, but such capabilities may be inapplicable given the EHR Module's anticipated function and/or point of integration.

In response to the comment regarding the assessment of privacy and security certification criteria by testing labs, we anticipate that an EHR Module developer would request a testing lab to only test the privacy and security certification criteria to which the EHR Module developer believes are appropriate for its EHR Module. In other words, a testing lab would test what is requested by an EHR Module developer and not be responsible for determining whether other privacy and security certification criteria (not requested for testing) may in fact be applicable or technically feasible for the EHR Module developer to implement. This responsibility would be an ONC–ACB's and, for the purposes of certification, we require that an individual or entity that presents an EHR Module for certification must provide sufficient documentation to the ONC–ACB to support its assertion that a particular privacy and security certification criterion is inapplicable or that satisfying the certification criterion is technically infeasible. Based on this documentation, the ONC–ACB shall independently assess and make a reasonable determination as to whether the EHR Module should be exempt from having to satisfy particular privacy or security certification criteria. As a result, there could be situations where despite an EHR Module developer's belief that a privacy and security certification criterion is inapplicable or technically infeasible an ONC–ACB makes a determination to the contrary. We believe that these instances would be the exception and not the rule but, nonetheless, we encourage EHR Module developers to carefully consider those privacy and security certification criteria they believe are inapplicable or technically infeasible prior to seeking testing. Finally, we recognize that this approach provides a certain amount of discretion among the ONC–ACBs, but we believe that any inconsistent application that emerges could be mitigated by guidance from the National Coordinator.

A commenter expressed a concern about the overall privacy and security of a combination of EHR Modules. As we stated in the Proposed Rule and the HIT Standards and Certification Criteria interim final rule, it is incumbent on the eligible professional or eligible hospital to ensure that a combination of EHR Modules properly work together to meet all of the required capabilities necessary to meet the definition of Certified EHR Technology. Thus, the flexibility and customization provided through the use of EHR Modules may also include some additional work on the part of an eligible professional or eligible hospital to ensure that adopted EHR Modules properly work together. Alternatives to this custom approach, as we have discussed, include the adoption of Complete EHRs and pre-coordinated, integrated bundles of EHR Modules.

We also agree with the commenter who stated that we should remove the third exception and simply require all EHR Modules, if not included in a pre-coordinated integrated bundle, to follow the same approach. As a result, and as we did in the context of the temporary certification program, only the first and second exception of proposed § 170.550(c) will be finalized. We recognize that, with respect to an EHR Module that is focused exclusively on providing one or more privacy and security capabilities, the remaining privacy and security certification criteria may be inapplicable or compliance with them may be technically infeasible. However, we do not believe it is prudent to presume that this will always be the case.

Comments. Several commenters asked for clarification of the circumstances under which the first exception we proposed applied in relation to a pre-coordinated, integrated bundle of EHR Modules, the carve out to this exception related to EHR Modules that were "not be part of a local system," and our use of the term "end user."

Response. Overall, the premise behind the first exception is to omit the general requirement that each individual EHR Module must be certified to all of the adopted privacy and security criteria. We believe it would be pragmatic to eliminate this requirement in situations where several EHR Module developers (*e.g.,* different vendors) or a single EHR Module developer presents a collection of EHR Modules as a pre-coordinated, integrated bundle to an ONC–ACB for

certification. In these circumstances, the pre-coordinated, integrated bundle of EHR Modules would otherwise meet the definition of and constitute a Complete EHR. Therefore, consistent with our approach in the Temporary Certification Program final rule, we clarify that in the circumstances where a pre-coordinated, integrated bundle of EHR Modules is presented for certification and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules, that those other EHR Modules would be exempt from being certified to the adopted privacy and security certification criteria. To illustrate, four EHR Module developers each develop one EHR Module (EHR Modules A, B, C, and D) and form an affiliation. The EHR Module developers present their EHR Modules for certification as a pre-coordinated, integrated bundle and identify that EHR Module "C" is responsible for providing the privacy and security capabilities for the rest of the entire bundle (EHR Modules A, B, and D). In this scenario, EHR Modules A, B, and D would be exempt from also being certified to the adopted privacy and security certification criteria.

With respect to the proposed carve out to this exception related to EHR Modules that would "not be part of a local system," we sought to limit those circumstances where a group of EHR Module developers could claim that a collection of EHR Modules was a "pre-coordinated, integrated bundle," yet it would be technically infeasible for one or all of the EHR Modules in the collection to be demonstrably responsible for providing all of the privacy and security capabilities for the rest of the EHR Modules. We believe this would occur in situations where a "pre-coordinated, integrated bundle" of EHR Modules includes one or more services offered by different EHR Module developers that have been implemented on different technical architectures or hosted over the Internet on one or multiple different servers. In this situation we do not believe that it would be possible for one or more of the EHR Modules to be demonstrably responsible for providing all of the privacy and security capabilities for the rest of the EHR Modules. For example, we do not believe that it is possible, at the present time, for a web-based EHR Module to offer authentication for another EHR Module that may be installed on an eligible professional's laptop, nor do we believe that one or more web-based services could provide an audit log for actions that took place outside of that service.

We believe that with this additional clarity the explicit mention of the first exception's carve out is no longer necessary and have revised the first exception accordingly to include the clarifying concepts we discuss above. This revision has also resulted in the removal of the term "end user," which commenters requested we clarify. We are redesignating proposed § 170.550(c) as § 170.550(e). The entire provision at § 170.550(e), including the changes from both of our responses above, will read:

EHR Modules shall be certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion. We made similar modifications to § 170.450(c) in the Temporary Certification Program final rule.

We would like to clarify a few points related to pre-coordinated, integrated bundles of EHR Modules. First, a pre-coordinated, integrated bundle of EHR Modules will qualify for the exception at § 170.550(e)(1) if, and only if, the bundle would otherwise meet the definition of and constitute a Complete EHR. In other words, the pre-coordinated, integrated bundle of EHR Modules must meet, at a minimum, all of the applicable certification criteria adopted by the Secretary in subpart C of part 170, even though the bundle and its constituent EHR Modules would not have been developed as a Complete EHR. For example, three EHR Modules may be integrated and "bundled" together, but if the bundle does not satisfy all of the applicable certification criteria that have been adopted, it will not qualify for this specific exception. In those cases, we would view such a bundle as an EHR Module that provides multiple capabilities. Second, because a pre-coordinated, integrated bundle of EHR Modules would otherwise meet the definition of and constitute a Complete EHR, we expect to list it as a "Complete EHR" and not an "EHR Module" on the CHPL, but would provide a designation noting that it is a pre-coordinated, integrated bundle of EHR Modules. Based on experience, we may determine that a more effective method for listing pre-coordinated, integrated bundles of EHR Modules on the CHPL would be appropriate and will periodically evaluate if another method would be beneficial. As previously discussed in this preamble, we expect ONC–ACBs will specifically identify pre-coordinated, integrated bundles of EHR Modules as part of their reporting obligations under § 170.523(f). Finally, in case it is unclear from the context, we clarify that references to EHR Module(s) in other provisions of § 170.550 are intended to include pre-coordinated, integrated bundles of EHR Modules.

Comments. A few commenters requested that we clarify whether there could be specific privacy and security-focused EHR Modules. That is, in the context of the definition of EHR Module, whether we intended to permit EHR Modules to exist that only addressed one or more adopted privacy and security certification criteria. One commenter asked for clarification as to whether a specific privacy and security-focused EHR Module would meet a certification criterion if its purpose was to call or assign the actual capability required by a certification criterion to another function or service.

Response. Yes, as we stated in the Temporary Certification Program final rule, we believe that there could be specific privacy and security-focused EHR Modules and do not preclude such EHR Modules from being presented for certification. However, with respect to the second comment and request for clarification, we believe that an EHR Module itself must be capable of performing a capability required by an adopted privacy and security certification criterion and that delegating the responsibility to another service or function would not be acceptable. In those cases, there would be no proof that the EHR Module could actually perform the specific capability, only that it could direct another service or function to do it.

c. Identification of Certified Status

We proposed in § 170.550(d) to require ONC–ACBs authorized to certify EHR Modules to clearly indicate the certification criterion or criteria to which an EHR Module has been certified in the EHR Module's certification documentation.

Comments. We received two comments requesting that we standardize the certification documentation requirements or at least provide clear guidelines for "certificate" design. The commenters were concerned that if left to the discretion of ONC–ACBs, the resulting certification "certificates" could look quite different and result in marketplace confusion. One commenter recommended that the certification "certificate," which will figure prominently in EHR software vendor marketing, should be uniform in appearance and depict HHS authority and assurance.

Response. We agree with the commenters that "certificate" documentation should be designed in a way that does not lead to market confusion. Therefore, we are establishing a new Principle of Proper Conduct for ONC–ACBs regarding the proper identification of Complete EHRs and EHR Modules, similar to the new Principle of Proper Conduct for ONC–ATCBs we finalized in the Temporary Certification Program final rule. We further discuss the basis for this new Principle of Proper Conduct for ONC–ACBs under the heading titled "*O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status*" later in this preamble. Consistent with this decision, we are modifying § 170.550 to remove proposed paragraph (d). This modification will eliminate any potential redundancy with the new Principle of Proper Conduct on the proper identification of Complete EHRs and EHR Modules.

3. Other Types of HIT

We proposed in § 170.553 that an ONC–ACB could be authorized to certify HIT, other than Complete EHRs and/or EHR Modules, in accordance with the applicable certification criterion or criteria adopted by the Secretary at subpart C of part 170. In association with this proposed provision, we invited public comment on the need for additional HIT certifications, the types of HIT that would be appropriate for certification, and on any of the potential benefits or challenges associated with certifying other types of HIT.

Comments. We received numerous comments on our proposal to utilize the permanent certification program for the certification of other types of HIT, with commenters overwhelmingly in favor of this proposal. Commenters also made suggestions of other types of HIT that could be certified, such as personal health records, health information organizations, pharmacy and laboratory systems, ancillary clinical systems including radiology information systems, picture archiving and communication systems, cardiology systems, vital signs and point-of-care medical devices, and telehealth and remote patient care solutions. Conversely, a few commenters did not believe that there was a current need for the certification of other types of HIT and suggested that we should first determine whether a private market would develop for the certification of other types of HIT. A few other commenters suggested that the permanent certification program should first focus on the certification of Complete EHRs and EHR Modules and that further certification of other types of HIT should be done with the intent of supporting meaningful use efforts.

Response. We appreciate the support for the certification of other types of HIT under the permanent certification program. Consistent with our discussion in the Proposed Rule, we maintain that section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a voluntary certification program or programs for other types of HIT besides Complete EHRs and EHR Modules. We agree with the commenters, however, that the initial focus of the permanent certification program should be on the certification of Complete EHRs and EHR Modules in support of efforts by eligible professionals and eligible hospitals who seek to demonstrate meaningful use under the Medicare and Medicaid EHR Incentive Programs. Moreover, as we stated in the Proposed Rule, the Secretary must first adopt certification criteria applicable to other types of HIT before the National Coordinator could subsequently authorize an ONC–ACB to certify such HIT under the permanent certification program. In the event that the Secretary adopts such applicable certification criteria and future circumstances suggest the need or demand for the certification of other types of HIT, we will further consider the comments received in determining how to proceed, including those comments suggesting specific types of other HIT that would be appropriate for certification. As previously noted in this preamble, if the scope of the permanent certification program is eventually expanded to include other types of HIT, certification would not constitute a replacement or substitution for other Federal requirements that may be applicable to those other types of HIT. Consistent with this discussion, we are finalizing § 170.553 without modification.

J. Certification of "Minimum Standards"

In the Proposed Rule, we summarized the approach set forth in the HIT Standards and Certification Criteria interim final rule (75 FR 2014) to treat certain vocabulary code set standards as "minimum standards." We noted that the establishment of "minimum standards" for specific adopted code sets would, in certain circumstances, allow a Complete EHR and/or EHR Module to be tested and certified to a permitted newer version of an adopted code set without the need for additional rulemaking. Additionally, we noted that this approach would enable Certified EHR Technology to be upgraded to a permitted newer version of a code set without adversely affecting its certified status.

At the end of this summary, we reiterated a previously identified limitation of the "minimum standards" approach with respect to significant revisions to adopted code sets. We stated that a newer version of an adopted "minimum standard" code set would be permitted for use in testing and certification unless it was a significant revision to a code set that represented a "modification, rather than maintenance or a minor update of the code set." In those cases, we reiterated that the Secretary would likely proceed with notice and comment rulemaking to adopt a significantly revised code set standard.

We proposed two methods through which the Secretary could identify new versions of adopted "minimum standard" code sets. The first method would allow any member of the general public to notify the National Coordinator about a new version. Under the second method, the Secretary would proactively identify newly published versions. After a new version has been identified, a determination would be issued as to whether the new version constitutes maintenance efforts or minor updates to the adopted code set and consequently may be permitted for use in certification. We proposed, as described in § 170.555, that once the Secretary has accepted a new version of an adopted "minimum standard" code set that:

(1) Any ONC–ACB may test and certify Complete EHRs and/or EHR Modules according to the new version;

(2) Certified EHR Technology may be upgraded to comply with the new version of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology; and

(3) ONC–ACBs would not be required to test and certify Complete EHRs and/or EHR Modules according to the new version until we updated the incorporation by reference of the adopted version to a newer version.

Finally, we stated that for either method, we would regularly publish on a quarterly basis, either by presenting to the HIT Standards Committee or by posting a notification on our Web site, any Secretarial determinations that have been made with respect to "minimum standard" code sets. We requested public comment on the frequency of publication, any other approaches we should consider to identify newer versions of adopted code set standards, and whether both methods described above should be used.

Comments. Many commenters supported our proposed approaches. These commenters also encouraged us to pursue both of the proposed approaches (notification of the National Coordinator by the general public and proactive identification by the Secretary). Some commenters recommended that we establish open lines of communication with the organizations responsible for maintaining identified "minimum standard" code sets in order to facilitate the process of identifying newer versions.

Response. We appreciate the commenters' support for our proposals. We first note that we inadvertently referenced "testing" in proposed § 170.555. As specified in this final rule, the National Coordinator will authorize ONC–ACBs to perform certifications and not testing under the permanent certification program. Therefore, we are removing references to "testing" in § 170.555. Second, based on the commenters' feedback, we have decided to adopt both of the proposed approaches for the permanent certification program, as we did for the temporary certification program. In addition, we expect to work, as appropriate, with the maintenance organizations for the "minimum standard" code sets, as well as the HIT Standards Committee, to identify new versions when they become available.

Comments. A few commenters recommended that ONC–ACBs not be required to use an accepted newer version of a "minimum standard" code set for certification. Along those lines, a few other commenters recommended that there be a delay period between the Secretary's acceptance of a new version and when it would be required for certification. One commenter noted that supporting multiple versions of standards should be avoided and that there would be differences in what was certified versus what was implemented, while another commenter noted that even permitting the use of a minor update could affect interoperability. Some commenters specifically requested clarification regarding the timeline associated with the Secretary's acceptance of a newer version and its publication and what requirement there would be for its inclusion in certification.

Response. We believe that some commenters misunderstood the implications of the Secretary's acceptance of a newer version of a "minimum standard" code set. We therefore clarify that if the Secretary accepts a newer version of a "minimum standard" code set, *nothing is required* of ONC–ACBs, Complete EHR or EHR Module developers, or the eligible professionals and eligible hospitals who have implemented Certified EHR Technology. We provided similar clarification for the temporary certification program in the final rule establishing that program. In the Proposed Rule, we used a three-pronged approach in order to provide greater flexibility and accommodate industry practice with respect to code sets that must be maintained and frequently updated. The first prong would permit, but *not require,* ONC–ACBs to use an accepted newer version of a "minimum standard" code set to certify Complete EHRs and/or EHR Modules if the accepted newer version has been incorporated into a product by a Complete EHR or EHR Module developer. In these instances, we believe this approach benefits Complete EHR or EHR Module developers because they would be able to adopt a newer version of a code set voluntarily and have their Complete EHR or EHR Module certified according to it, rather than having to use an older version for certification. The second prong would permit, but *not require,* eligible professionals and eligible hospitals who are already using Certified EHR Technology to receive an upgrade from their Complete EHR or EHR Module developer or voluntarily upgrade themselves to an accepted newer version of a "minimum standard" code set without adversely affecting the certification status of their Certified EHR Technology. Again, we believe this is a benefit to eligible professionals and eligible hospitals and provides greater flexibility. The third prong explicitly states that an ONC–ACB would not be required to use any other version of a "minimum standard" code set beyond the one adopted at 45 CFR 170 subpart B until the Secretary incorporates by reference a newer version of that code set.

We recognize that a few different versions of adopted "minimum standards" could all be implemented at the same time and before a subsequent rulemaking potentially changes what constitutes the "minimum." We also understand the point raised by the commenter who expressed concerns about this approach because it could potentially create a situation where there could be differences in what was certified versus what was implemented. Along those lines, we also appreciate the point made by the commenter that a minor update could affect interoperability. We acknowledge these concerns and considered them as part of our analysis in determining whether to adopt minimum standards and to permit such standards to be exceeded when newer versions had been made available for use. However, we would like to make clear that we provide this flexibility on a voluntary basis and believe that the benefit of accepting newer versions of a "minimum standard" (namely, enabling the HIT industry to keep pace with new code sets) outweighs any potential or temporary risk to interoperability.

In light of the discussion above, we do not believe it is necessary to change any of our proposals, and we hope the additional clarification above addresses the concerns and questions raised by commenters. Accordingly, except for removing references to "testing," we are finalizing § 170.555 without modification.

Comments. Some commenters requested that we clarify the process the Secretary would follow before accepting a newer version of an adopted "minimum standard" code set, including specifying the timeframes for publication.

Response. We expect that after a new version of an adopted "minimum standard" code set has been identified (either through the general public's notification of the National Coordinator or the Secretary proactively identifying its availability), the National Coordinator would ask the HIT Standards Committee to assess and solicit public comment on the new version. We expect that the HIT Standards Committee would subsequently issue a recommendation to the National Coordinator which would identify whether the Secretary's acceptance of the newer version for voluntary implementation and certification would burden the HIT industry, negatively affect interoperability, or cause some other

type of unintended consequence. After considering the recommendation of the HIT Standards Committee, the National Coordinator would determine whether or not to seek the Secretary's acceptance of the new version of the adopted "minimum standard" code set. If the Secretary approves the National Coordinator's request, we would issue guidance on an appropriate but timely basis indicating that the new version of the adopted "minimum standard" code set has been accepted by the Secretary.

K. Authorized Certification Methods

We proposed in § 170.557 that, as a primary method, an ONC–ACB would be required to be capable of certifying Complete EHRs and/or EHR Modules at its facility. We also proposed that an ONC–ACB would be required to have the capacity to certify Complete EHRs and/or EHR Modules through one of the following secondary methods: at the site where the Complete EHR or EHR Module has been developed; or at the site where the Complete EHR or EHR Module resides; or remotely (*i.e.,* through other means, such as through secure electronic transmissions and automated web-based tools, or at a location other than the ONC–ACB's facility).

Comments. We received many comments on our proposal. We received varying recommendations and proposals, but the majority of commenters did not agree with certification at an ONC–ACB's facility as the primary method. Commenters noted that to require eligible professionals or eligible hospitals with self-developed Complete EHRs to physically move their Complete EHRs to another location for certification would not only be burdensome but in many cases impossible. Instead, many commenters recommended that we require ONC–ACBs to have the capacity to certify products through all of the secondary methods we proposed. Some commenters supported secondary methods without preference, while many commenters recommended that we require ONC–ACBs to offer remote certification as the primary method because of its efficiency and low cost to Complete EHR and EHR Module developers. Commenters also noted that ONC–ACBs could offer other methods, including performing certification at an ONC–ACB's facility. One commenter recommended that, as the primary method, ONC–ACBs should be required to support certification at the Complete EHR or EHR Module developer's site, which could include a development or deployment site. Another commenter stated that each method should be considered equal because different methods may be appropriate for different developers. Some commenters recommended that we clarify whether we expected Complete EHRs and EHR Modules to be "live" at customer sites before they can be certified. The commenters asserted that such a prerequisite will significantly delay the roll out of customer upgrades.

Response. We appreciate the many options and preferences expressed by the commenters. We believe that in order to adequately and appropriately address the commenters' concerns, an ONC–ACB must have the capacity to provide remote certification for both development and deployment sites. For the purposes of the permanent certification program, a development site is the physical location where a Complete EHR, EHR Module or other type of HIT was developed. For the purposes of the permanent certification program, a deployment site is the physical location where a Complete EHR, EHR Module or other type of HIT resides or is being or has been implemented. As discussed in the Proposed Rule, remote certification would include the use of methods that do not require the ONC–ACB to be physically present at the development or deployment site. This could include the use of web-based tools or secured electronic transmissions. In addition to remote certification, an ONC–ACB may also offer certification at its facility or at the physical location of a development or deployment site, but we are not requiring that an ONC–ACB offer such certification. As indicated by commenters and our own additional research, the market currently utilizes predominantly remote methods for the certification of HIT. On-site certification was cited as costly and inefficient. Therefore, consistent with our requirements of ONC–ATCBs under the temporary certification program, we are not requiring ONC–ACBs to offer such certification, but anticipate that some ONC–ACBs will offer on-site certification if there is a market demand. In response to those commenters who requested clarification regarding "live" certification, we want to make clear that we do not believe that a Complete EHR, EHR Module or other type of HIT must be "live at a customer's site" in order to qualify for certification by an ONC–ACB. As stated above, a Complete EHR, EHR Module or other type of HIT could be certified at the development site of a developer of Complete EHRs, EHR Modules or other types of HIT. Consistent with this discussion, we are revising § 170.557 to require an ONC–ACB to provide remote certification for both development and deployment sites and have included the definitions of "development site," "deployment site," and "remote certification" in § 170.502.

L. Good Standing as an ONC–ACB, Revocation of ONC–ACB Status, and Effect of Revocation on Certifications Issued by a Former ONC–ACB

We proposed requirements that ONC–ACBs would need to meet in order to maintain good standing under the permanent certification program, the processes for revoking an ONC–ACB's status for failure to remain in good standing, the effects that revocation would have on a former ONC–ACB, and the potential effects that revocation could have on certifications issued by a former ONC–ACB.

1. Good Standing as an ONC–ACB

We proposed in § 170.560 that, in order to maintain good standing, an ONC–ACB would be required to adhere to the Principles of Proper Conduct for ONC–ACBs; refrain from engaging in other types of inappropriate behavior, including misrepresenting the scope of its authorization or certifying Complete EHRs and/or EHR Modules for which it was not given authorization; and follow all applicable Federal and State laws.

Comments. Commenters expressed appreciation for our proposed standards of conduct for ONC–ACBs. One commenter encouraged us to evaluate compliance with the Principles of Proper Conduct on an ongoing basis and at the time for "re-authorization," particularly if either a Type-1 or Type-2 violation had occurred.

Response. We believe that our proposed Principles of Proper Conduct for ONC–ACBs are essential to maintaining the integrity of the permanent certification program, as well as ensuring public confidence in the program and the Complete EHRs, EHR Modules, and other types of HIT that may be certified under the program. We intend to monitor compliance with the Principles of Proper Conduct for ONC–ACBs on an ongoing basis by, among other means, ensuring that ONC–ACBs are attending all mandatory ONC training. It is also expected that ONC–ACBs will maintain relevant documentation of their compliance with the Principles of Proper Conduct for ONC–ACBs because such documentation would be necessary, for instance, to rebut a notice of noncompliance with the Principles of Proper Conduct issued by the National Coordinator under § 170.565. At the time of renewal, an ONC–ACB will be assessed based on the updated

application it provides in accordance with § 170.540, which would entail reviewing an ONC–ACB's current accreditation and adherence to the Principles of Proper Conduct. Accordingly, we are finalizing § 170.560 without modification.

2. Revocation of ONC–ACB Status

We proposed in § 170.565 that the National Coordinator could revoke an ONC–ACB's status if it committed a Type-1 violation or if it failed to timely or adequately correct a Type-2 violation. We defined Type-1 violations to include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the permanent certification program, a program administered by HHS or any program administered by the Federal government.

We defined Type-2 violations as noncompliance with § 170.560, which would include without limitation, failure to adhere to the Principles of Proper Conduct for ONC–ACBs, engaging in other types of inappropriate behavior, or failing to follow other applicable laws. We proposed that if the National Coordinator were to obtain reliable evidence that an ONC–ACB may no longer be in compliance with § 170.560, the National Coordinator would issue a noncompliance notification. We proposed that an ONC–ACB would have 30 days from receipt of a noncompliance notification to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation had been corrected. We further proposed that the National Coordinator would have up to 30 days from the time the response is received to evaluate the response and determine whether a violation had occurred and whether it had been adequately corrected.

We proposed that the National Coordinator could propose to revoke an ONC–ACB's status if the ONC–ACB committed a Type-1 violation. We proposed that the National Coordinator could propose to revoke an ONC–ACB's status if, after an ONC–ACB has been notified of a Type-2 violation, the ONC–ACB fails to rebut an alleged Type-2 violation with sufficient evidence showing that the violation did not occur or that the violation had been corrected, or if the ONC–ACB did not submit a written response to a Type-2 noncompliance notification within the specified timeframe. We proposed that an ONC–ACB would have up to 10 days from receipt of the proposed revocation notice to submit a written response explaining why its status should not be revoked. We proposed that the National Coordinator would have up to 30 days from the time the response is received to review the information submitted by the ONC–ACB and reach a decision. We further proposed that an ONC–ACB would be able to continue its operations under the permanent certification program during the time periods provided for the ONC–ACB to respond to a proposed revocation notice and the National Coordinator to review the response.

We proposed that if the National Coordinator determined that an ONC–ACB's status should not be revoked, the National Coordinator would notify the ONC–ACB's authorized representative in writing of the determination. We also proposed that the National Coordinator could revoke an ONC–ACB's status if it is determined that revocation is appropriate after considering the ONC–ACB's response to the proposed revocation notice or if the ONC–ACB did not respond to a proposed revocation notice within the specified timeframe. We further proposed that a decision to revoke an ONC–ACB's status would be final and not subject to further review unless the National Coordinator chose to reconsider the revocation.

We proposed that a revocation would be effective as soon as the ONC–ACB received the revocation notice. We proposed that a certification body that had its ONC–ACB status revoked would be prohibited from accepting new requests for certification and would be required to cease its current certification operations under the permanent certification program. We further proposed that if a certification body had its ONC–ACB status revoked for a Type-1 violation, it would be prohibited from reapplying for ONC–ACB status under the permanent certification program for one year.

We proposed that failure to promptly refund any and all fees for uncompleted certifications of Complete EHRs and EHR Modules after the revocation of ONC–ACB status would be considered a violation of the Principles of Proper Conduct for ONC–ACBs. We proposed that the National Coordinator would consider such violations in the event that a certification body reapplied for ONC–ACB status under the permanent certification program.

In association with these proposals, we specifically requested that the public comment on three additional proposals. First, we requested that the public comment on whether the National Coordinator should consider proposing the revocation of an ONC–ACB's status for repeatedly committing Type-2 violations even if the ONC–ACB adequately corrected the violations each time. In conjunction with this request, we asked how many corrected Type-2 violations would be sufficient for proposing revocation of an ONC–ACB and to what extent the frequency of these violations should be a consideration. Second, we requested that the public comment on whether the proposed 1-year bar on reapplying for ONC–ACB status imposed on a revoked certification body should be shortened or lengthened and whether alternative sanctions should be considered. In addition we noted that, depending on the type of violation that led to the former ONC–ACBs status being revoked, it was possible that the former ONC–ACB would also lose its accreditation. Third, we requested that the public comment on whether the National Coordinator should also include a process to suspend an ONC–ACB's status.

Comments. We received general support for our proposed revocation process with commenters encouraging us to take a stringent position regarding Type-1 and Type-2 violations out of concern that a lack of confidence in the qualifications or integrity of an ONC–ACB could seriously undermine the permanent certification program's objectives. Commenters requested that developers of HIT and eligible professionals and eligible hospitals be notified if an ONC–ACB is suspended, the National Coordinator proposes to revoke an ONC–ACB's status, and/or an ONC–ACB's status is revoked.

A commenter recommended that there not be a "broad" categorical Type-1 violation bar on reapplying for ONC–ACBs that had their status revoked. A few commenters suggested a shorter bar on reapplying could be possible if the organization demonstrated good faith and timely addressed the reasons for revocation, while other commenters supported the proposed 1-year bar or extending the bar to at least three years. Commenters recommending a longer bar on reapplying reasoned that a longer bar would be a stronger deterrent and provide sufficient time for a certification body to "re-organize" itself. These commenters also recommended that a "re-authorized" former ONC–ACB serve a probationary period. A commenter recommended that an ONC–ACB should have its accreditation permanently revoked if it commits three Type-1 violations. The commenter also noted that it was unlikely that the market

would support an ONC–ACB that committed repeated violations.

We received a few comments on whether we should revoke an ONC–ACB's status for committing multiple Type-2 violations even if the violations were corrected. A couple of commenters suggested that an ONC–ACB should have its status revoked for committing multiple violations. One commenter recommended that the National Coordinator retain the discretion to review and judge each situation as opposed to setting a certain threshold for automatic revocation.

We received multiple comments on our proposed alternative of a suspension process with all of the commenters suggesting that there could be value in a suspension process. One commenter stated that our goal should be first and foremost to protect the needs of product purchasers and patients. Commenters stated that suspension could be warranted in lieu of proposing revocation and/or during the period between a proposed revocation and a final decision on revocation. Some commenters recommended that an ONC–ACB be allowed to continue operations during a suspension or be provided "due process" rights before being suspended, while other commenters suggested that allowing an ONC–ACB to continue during instances where an investigation is ongoing and violations are being resolved could jeopardize the industry's confidence level in the certification process. One commenter suggested that an ONC–ACB be allowed to continue operations unless the alleged violation would or could adversely impact patient safety and/or quality of care. Some commenters also requested that the fees paid by a Complete EHR and/or EHR Module developer for certification be refunded if the ONC–ACB is suspended.

Response. We believe that Type-1 violations as described are not too "broad" in that they must also "threaten or significantly undermine the integrity of the permanent certification program." As noted in the Proposed Rule, we believe such a violation could significantly undermine the public's faith in our permanent certification program. Therefore, we believe that revocation and barring a former ONC–ACB from reapplying for ONC–ACB status is an appropriate remedy. In reaching any conclusion to revoke an ONC–ACB's status, we believe that we have provided appropriate due process (*i.e.,* an appropriate appeals process).

We noted in the Temporary Certification Program final rule that we believed a 1-year bar on reapplying for ONC–ACB status was appropriate for the temporary certification program, but we would reconsider the appropriate length of the bar and whether a probationary period would be appropriate for the permanent certification program. Having considered these issues in the context of the permanent certification program, we continue to believe that a 1-year bar on reapplying is appropriate and have adopted this position for the permanent certification program. We believe that the l-year bar on reapplying will allow the former ONC–ACB a sufficient amount of time to address the reasons for the Type-1 violation before reapplying. In addition, when assessing a former ONC–ACB's application for "reinstatement," we will be able to determine if the applicant is accredited by the ONC–AA. The accreditation process, itself, will be managed by the ONC–AA in accordance with ISO 17011. The ONC–AA will be responsible for determining appropriate sanctions for non-conformance with accreditation requirements in accordance with ISO 17011 and its accreditation program. However, considering accreditation is a requirement to become an ONC–ACB, we believe that accreditation will be another means of ensuring that a former ONC–ACB has fully addressed the reasons for revocation and, therefore, do not believe that a "probationary period" will be necessary. Once "re-authorized," an ONC–ACB will be subject to the same requirements for maintaining its status and consequences for not adhering to those requirements.

We do not believe that it is appropriate to initiate revocation proceedings against an ONC–ACB for any amount of corrected Type-2 violations under the permanent certification program. We did not originally propose to initiate revocation proceedings for multiple corrected Type-2 violations, but requested public comment on the possibility. Commenters appeared to agree that initiating revocation proceedings against an ONC–ACB for committing multiple Type-2 violations, even if corrected, was an acceptable proposition under certain conditions. While we agree that committing multiple Type-2 violations, even if corrected, is cause for concern, it would be difficult to establish a sufficiently objective and equitable standard for initiating revocation proceedings on that basis against an ONC–ACB. As evidenced by the comments, it is difficult to determine the appropriate number of corrected Type-2 violations that would lead to revocation proceedings. An ONC–ACB could commit and correct two Type-2 violations involving a missed training or a timely update to ONC on a key personnel change. In such a situation, we do not believe that automatically initiating revocation proceedings would be warranted. We also do not believe it would be appropriate to adopt the one commenter's recommendation to allow the National Coordinator to use discretion to address such instances. This would not give an ONC–ACB sufficient notice of what Type-2 violation, even if corrected, could lead to revocation proceedings nor an indication of the amount or frequency of the violations that could lead to revocation proceedings. Therefore, we believe that an ONC–ACB should remain in good standing if it sufficiently corrects a Type-2 violation, no matter how many times an ONC–ACB commits a Type-2 violation. Violations will be a matter of public record that, as noted by a commenter, may influence Complete EHR, EHR Module and HIT developers' decisions on which ONC–ACB to select for the certification of their Complete EHRs, EHR Modules and/or other types of HIT.

We agree with the commenters that suspension could be an effective way to protect purchasers of certified products and ensure patient health and safety. As a result, we agree with the commenter and believe that the National Coordinator should have the ability to suspend an ONC–ACB's operations under the permanent certification program when there is reliable evidence indicating that the ONC–ACB committed a Type-1 or Type-2 violation and that the continued certification of Complete EHRs, EHR Modules and/or other types of HIT could have an adverse impact on patient health or safety. As mentioned in the Proposed Rule, the National Coordinator's process for obtaining reliable evidence would involve one or more of the following methods: fact-gathering; requesting information from an ONC–ACB; contacting an ONC–ACB's customers; witnessing an ONC–ACB perform certification; and/or reviewing substantiated complaints.

Due to the disruption a suspension may cause for an ONC–ACB, and more so for the market, we believe that suspension is appropriate in only the limited circumstances described above and have revised § 170.565 to provide the National Coordinator with the discretion to suspend an ONC–ACB's operations accordingly. An ONC–ACB would first be issued a notice of proposed suspension. Upon receipt of a notice of proposed suspension, an ONC–ACB will be permitted up to 3

days to submit a written response to the National Coordinator explaining why its operations should not be suspended. The National Coordinator will be permitted up to 5 days to review the ONC–ACB's response and issue a determination. In the determination, the National Coordinator will either rescind the proposed suspension, suspend the ONC–ACB's operations until it has adequately corrected a Type-2 violation, or propose revocation in accordance with § 170.565(c) and suspend the ONC–ACB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC–ACB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC–ACB's receipt of a notice of suspension. We believe that this process addresses both the commenters' concerns about due process and about maintaining the industry's confidence in the permanent certification program by not allowing an ONC–ACB to continue operations while an investigation is ongoing and/or violations are being resolved related to patient health or safety.

We are designating the new suspension provision as paragraph (d) of § 170.565. Proposed paragraphs (d) through (g) are being redesignated as paragraphs (e) through (h), respectively. As discussed in a previous section of this preamble, we are revising § 170.523(j) to clarify that an ONC–ACB would have to refund any fees paid by a Complete EHR or EHR Module developer that seeks to withdraw a request for testing and certification while an ONC–ACB is suspended.

We intend to provide public notification via our Web site and list serve if an ONC–ACB is suspended, issued a notice proposing its revocation, and/or has its status revoked. We also note that we are revising § 170.565(c)(1) to state that "[t]he National Coordinator may propose to revoke an ONC–ACB's status if the National Coordinator has reliable evidence that the ONC–ACB committed a Type-1 violation." The term "reliable" was inadvertently left out of the provision in the Proposed Rule.

3. Effect of Revocation on Certifications Issued by a Former ONC–ACB

We proposed in § 170.570 to allow the certified status of Complete EHRs and/or EHR Modules certified by an ONC–ACB that subsequently had its status revoked to remain intact unless a Type-1 violation was committed that called into question the legitimacy of the certifications issued by the former ONC–ACB. In such circumstances, we proposed that the National Coordinator would review the facts surrounding the revocation of the ONC–ACB's status and publish a notice on ONC's Web site if the National Coordinator believed that Complete EHRs and/or EHR Modules were fraudulently certified by a former ONC–ACB and the certification process itself failed to comply with regulatory requirements. We further proposed that if the National Coordinator determined that Complete EHRs and/or EHR Modules were improperly certified, the "certified status" of affected Complete EHRs and/or EHR Modules would remain intact for 120 days after the National Coordinator published the notice. We specifically requested that the public comment on our proposed approach and the timeframe for re-certification.

Comments. Multiple commenters expressed agreement and understanding with the need to protect the integrity of the permanent certification program by ensuring the legitimacy of certifications issued by a former ONC–ACB and requiring recertification of Complete EHRs and/or EHR Modules where it is found that they were improperly certified. Many commenters stated, however, that we should only require recertification of the affected areas and elements and/or determine whether an improperly certified product negatively and substantially affected the performance of a Complete EHR or EHR Module in achieving a meaningful use objective before requiring recertification. Other commenters stated that "good faith" eligible professionals and eligible hospitals who can demonstrate meaningful use with a previously certified Complete EHR or EHR Module should continue to qualify for payments under the Medicare and Medicaid EHR Incentive Programs. Commenters further stated that providers should be allowed to wait and replace the previously certified product when new certification criteria have been finalized for the affected meaningful use criteria, or when their own strategic and technical requirements necessitate an upgrade, whichever comes first. Some commenters contended that the only overriding factor that should require recertification is if there is a demonstrable risk to patient safety from the use of improperly certified Complete EHRs and/or EHR Modules.

A few commenters expressed concerns about the potential negative financial impact recertification would have on Complete EHR and EHR Module developers, eligible professionals and eligible hospitals as well as the potential for legal liability related to eligible professionals and eligible hospitals making attestations to Federal and State agencies that they are using Certified EHR Technology.

Some commenters agreed with our 120-day proposal, while many commenters recommended 6, 9, 12, and 18-month "grace periods" for improperly certified Complete EHRs and/or EHR Modules. One commenter recommended an extension of the 120-day grace period if there were less than 6 ONC–ACBs at the time of decertification, which is the number of ONC–ACBs we estimate will exist under the permanent certification program.

Response. In instances where the National Coordinator determines that Complete EHRs and/or EHR Modules were improperly certified, we believe that recertification is necessary to maintain the integrity of the permanent certification program and to ensure the efficacy and safety of certified Complete EHRs and EHR Modules. By requiring recertification, eligible professionals and eligible hospitals as well as Complete EHR and EHR Module developers can have confidence in the permanent certification program and, more importantly, in the Complete EHRs and EHR Modules that are certified under the program. As we stated in the Proposed Rule, we believe it would be an extremely rare occurrence for an ONC–ACB to have its status revoked *and* for the National Coordinator to determine that Complete EHRs and/or EHR Modules were improperly certified. If such events were to occur, the regulatory provisions enable the National Coordinator to focus recertification on specific Complete EHRs and/or EHR Modules that were improperly certified in lieu of requiring recertification of all Complete EHRs and EHR Modules certified by the former ONC–ACB.

In this regard, the National Coordinator has a statutory responsibility to ensure that Complete EHRs and EHR Modules certified under the permanent certification program are in compliance with the applicable certification criteria adopted by the Secretary. We do not believe that the alternatives suggested by the commenters, such as whether a "good faith" eligible professional or eligible hospital can demonstrate meaningful use with a previously certified Complete EHR or EHR Module, would enable the National Coordinator to fulfill this statutory responsibility. Consequently, if the National Coordinator determines that a Complete EHR or EHR Module was improperly certified, then recertification by an ONC–ACB is the

only means by which to ensure that the Complete EHR or EHR Module satisfies the certification criteria. Moreover, an attestation by a Complete EHR or EHR Module developer and/or user of a Complete EHR or EHR Module would not be an acceptable alternative to recertification because the National Coordinator could not sufficiently confirm that all applicable certification criteria are met.

We appreciate the concerns expressed by commenters related to the potential financial burden of recertification, the potential legal liability for eligible professionals and eligible hospitals attesting to the use of Certified EHR Technology, and the perceived insufficient amount of time to have a Complete EHR and/or EHR Module recertified. We believe, however, that some of these concerns may be unfounded. Any decertification of a Complete EHR or EHR Module will be made widely known to the public by ONC through publication on our Web site and list serve, which we believe will help eligible professionals and/or eligible hospitals identify whether the certified status of their Certified EHR Technology is still valid. We also believe that programmatic steps, such as identifying ONC–ACB(s) that could be used for recertification, could be taken to assist Complete EHR and/or EHR Module developers with achieving timely and cost effective recertifications. Most importantly, in the rare circumstance that recertification is required, we believe that the need to protect the public from potentially unsafe Complete EHRs and/or EHR Modules outweighs the concerns expressed by the commenters. Accordingly, we are finalizing § 170.570 without modification.

M. Dual-Accredited Testing and Certification Bodies

In the Proposed Rule, we explained that the authorization given to ONC–ACBs by the National Coordinator would be valid only for performing certifications under the permanent certification program. We noted that this limitation was not intended to preclude an organization from also performing testing. In fact, we clarified that in order for a single organization (which may include subsidiaries or components) to perform both testing and certification under the permanent certification program it would need to be: 1) accredited by an ONC–AA and subsequently become an ONC–ACB; and 2) accredited under the NVLAP. We requested public comment on whether we should give organizations who are "dual accredited" and also become an ONC–ACB a special designation to indicate to the public that such an organization would be capable of performing both testing and certification under the permanent certification program.

Comments. We received a few comments expressing support for the concept of allowing organizations to conduct both testing and certification under the permanent certification program and giving a special designation to such organizations. Commenters stated that it would be convenient and efficient for Complete EHR and EHR Module developers if organizations are permitted to conduct both testing and certification. A commenter also noted that a special designation would provide clarity for the market.

Response. We agree with the commenters that organizations that are accredited and authorized to perform both testing and certification under the permanent certification program may be able to offer convenience and efficiencies as well as other benefits to HIT developers. We do note, however, that these types of organizations must adhere to the respective requirements of their accreditations. For instance, under the permanent certification program, ONC–ACBs must maintain their accreditation, which requires them to conform to Guide 65 at a minimum. Several different sections of Guide 65 require certification bodies to maintain impartiality in their organizational structure and practices. The impartiality requirement will safeguard against the risk that the certification component of an organization will be improperly influenced to certify HIT that has been tested by the testing component of that same organization.

We also agree with the commenters that a unique designation for organizations that are both ONC–ACBs and NVLAP-accredited testing labs is appropriate and will provide clarity to the market. We will indicate on our Web site those organizations that are both ONC–ACBs and NVLAP-accredited testing labs. We also suspect that such an organization will publicize its status as an ONC–ACB and NVLAP-accredited testing lab in an effort to increase market share.

N. Concept of "Self-Developed"

In the Proposed Rule, we interpreted the HIT Policy Committee's use of the word "self-developed" to mean a Complete EHR or EHR Module that has been designed, modified, or created by, or under contract for, a person or entity that will assume the total costs for its testing and certification and will be a primary user of the Complete EHR or EHR Module. We noted that self-developed Complete EHRs and EHR Modules could include brand new Complete EHRs or EHR Modules developed by a health care provider or their contractor. We further noted that "self-developed" could also include a previously purchased Complete EHR or EHR Module that is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary. We specifically stated that we would limit the scope of "modification" to only those capabilities for which the Secretary has adopted certification criteria because other capabilities (*e.g.,* a different graphical user interface (GUI)) would not affect the underlying capabilities a Complete EHR or EHR Module would need to include in order to be tested and certified. Accordingly, we stated that we would only refer to the Complete EHR or EHR Module as "self-developed" if the health care provider paid the total costs to have the Complete EHR or EHR Module tested and certified.

Comments. Multiple hospitals and hospital associations requested that we clarify the definition of "self-developed" to include an indication of the extent to which modifications may be made to previously certified Complete EHRs or EHR Modules without requiring a Complete EHR or EHR Module to be certified as "self-developed." The commenters noted that we have clearly stated that eligible professionals and eligible hospitals bear full responsibility for making certified EHR Modules work together. Therefore, the commenters contended that providers must be permitted to make necessary modifications to certified EHR Modules in order to fulfill that responsibility. The commenters stated that often there is a need for custom configurations or settings within the parameters of certified EHRs, including modifications that may be necessary to ensure that the EHR works properly when implemented within an organization's entire HIT environment. The commenters further stated that such modifications may affect, or even enhance, the capabilities addressed by the certification criteria by providing additional and specific decision-support functions or allowing for additional quality improvement activities. The commenters asserted that as long as the Complete EHR or EHR Module can still perform the function(s) for which it was originally certified, such modifications should not trigger a

requirement for the Complete EHR or EHR Module to be certified as self-developed, even if the changes affect the capabilities addressed by the certification criteria.

The commenters stated that clarity was needed due to the substantial resources that will be required for certification of self-developed systems. In addition, commenters stated that, for legal compliance purposes, clarity will enable providers to be confident in the attestations they submit to Federal and State agencies regarding the certification status of the EHR technology they use.

Response. As we stated in the Temporary Certification Program final rule, we understand the unique needs and requirements of eligible professionals and eligible hospitals with respect to the successful implementation and integration of HIT into operational environments. We provided a description of the term "self-developed" in the Proposed Rule's preamble for two main reasons. First, in order to provide greater clarity for stakeholders regarding who would be responsible for the costs associated with certification, and second, to clearly differentiate in our regulatory impact analysis those Complete EHRs and EHR Modules that would be certified once and most likely sold to many eligible professionals and eligible hospitals from those that would be certified once and used primarily by the person or entity who paid for the testing and certification. We believe that many commenters were not concerned about the fact that brand new, "built from scratch" self-developed Complete EHRs and EHR Modules would need to be certified. Rather, it appeared that commenters were concerned about whether any modification to a Complete EHR or EHR Module that had been certified already, including those modifications that would be enhancements or required to integrate several EHR Modules, would compromise the technology's certification or certifications and consequently require the eligible professional or eligible hospital to seek a new certification because the EHR technology would be considered self-developed. We believe this concern stems from the following statement we made in the preamble of the Proposed Rule:

"Self-developed Complete EHRs and EHR Modules could include brand new Complete EHRs or EHR Modules developed by a health care provider or their contractor. It could also include a previously purchased Complete EHR or EHR Module which is subsequently modified by the health care provider or their contractor and where such modifications are made to capabilities addressed by certification criteria adopted by the Secretary. We limit the scope of "modification" to only those capabilities for which the Secretary has adopted certification criteria because other capabilities (*e.g.,* a different graphical user interface (GUI)) would not affect the underlying capabilities a Complete EHR or EHR Module would need to include in order to be tested and certified."

In response to these concerns, we offer further clarification of the intent of our statements. We agree with commenters that not every modification would or should require a previously certified Complete EHR or EHR Module to be certified again as self-developed. We provided an example in the Proposed Rule, quoted above, regarding modifications that would not affect any of the capabilities addressed by the certification criteria adopted by the Secretary. In the Temporary Certification Program final rule, we acknowledged that a certified Complete EHR or EHR Module may not automatically meet a health care provider's needs when it is implemented in an operational environment. We also cautioned eligible professionals and eligible hospitals in the HIT Standards and Certification Criteria interim final rule that, if they choose to use EHR Modules to meet the definition of Certified EHR Technology, they alone would be responsible for properly configuring multiple EHR Modules in order to make them work together. Given that many of the certification criteria adopted by the Secretary express minimum capabilities, which may be added to or enhanced by eligible professionals and eligible hospitals to meet their health care delivery needs (*e.g.,* multiple rules could be added to the clinical decision support capability), we believe it is unrealistic to expect that the capabilities included within adopted certification criteria applicable to a Complete EHR or EHR Module will not be modified in some cases. As a result, we believe it is possible for an eligible professional or eligible hospital to modify a Complete EHR or EHR Module's capabilities for which certification criteria have been adopted without compromising the Complete EHR or EHR Module's certification. Stated differently, an eligible professional or eligible hospital's modifications to a certified Complete EHR or EHR Module would not automatically make the Complete EHR or EHR Module "self-developed" and consequently require the eligible professional or eligible hospital to obtain a new certification for the modified product. While we cannot review or address in this final rule every potential modification to determine whether it could possibly compromise a Complete EHR or EHR Module's certification, we strongly urge eligible professionals and eligible hospitals to consider the following. Certification is meant to provide assurance that a Complete EHR or EHR Module will perform according to the certification criteria to which it was tested and certified. Any modification to a Complete EHR or EHR Module after it has been certified has the potential to adversely affect the capabilities for which certification criteria have been adopted such that the Complete EHR or EHR Module no longer performs as it did when it was tested and certified, which in turn may compromise an eligible professional or eligible hospital's ability to achieve meaningful use. If an eligible professional or eligible hospital wants complete assurance that a Complete EHR or EHR Module's capabilities for which certification criteria have been adopted were not adversely affected by modifications that were made post-certification, they may choose to have the Complete EHR or EHR Module retested and recertified. Additionally, any post-certification modifications that adversely affect a Complete EHR or EHR Module's capabilities for which certification criteria have been adopted may be identified through surveillance conducted by an ONC–ACB.

O. Validity of Complete EHR and EHR Module Certification and Expiration of Certified Status

In the Proposed Rule, we discussed the validity of "certified status" of Complete EHRs and EHR Modules, as well as the expiration of that status as it related to the definition of Certified EHR Technology. We stated that certification represented "a snapshot, a fixed point in time, where it has been confirmed that a Complete EHR or EHR Module has met all applicable certification criteria adopted by the Secretary." We went on to say that as the Secretary adopts new or modified certification criteria, the previously adopted set of certification criteria would no longer constitute all of the applicable certification criteria to which a Complete EHR or EHR Module would need to be tested and certified. Thus, we clarified that after the Secretary has adopted new or modified certification criteria, a previously certified Complete EHR or EHR Module's certification would no longer be valid for purposes of meeting the definition of Certified EHR Technology. In other words, because new or modified certification criteria had been adopted, previously

issued certifications would no longer indicate that a Complete EHR or EHR Module possessed all of the capabilities necessary to support an eligible professional's or eligible hospital's achievement of meaningful use. Accordingly, we noted that Complete EHRs and EHR Modules that had been certified to the previous set of adopted certification criteria would no longer constitute "Certified EHR Technology."

We also discussed that the planned two-year schedule for updates to meaningful use objectives and measures and correlated certification criteria created a natural expiration with respect to the validity of a previously certified Complete EHR's or EHR Module's certified status and its continued ability to be used to meet the definition of Certified EHR Technology. We stated that after the Secretary has adopted new or modified certification criteria, previously certified Complete EHRs and EHR Modules must be recertified in order to continue to qualify as Certified EHR Technology.

With respect to EHR Modules, we noted that there could be situations where measures associated with a meaningful use objective may change, but the capability a certified EHR Module would need to provide would not change. As a result, we stated that it may be impracticable or unnecessary for the EHR Module to be re-certified. Therefore, we requested public comment on whether there should be circumstances where EHR Modules should not have to be re-certified.

We clarified that regardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Programs, the Certified EHR Technology that would need to be used must include the capabilities necessary to meet the most current set of certification criteria adopted by the Secretary at 45 CFR 170 subpart C in order to satisfy the definition of Certified EHR Technology. Finally, we asked for public comment on the best way to assist eligible professionals and eligible hospitals that begin meaningful use in 2013 or 2014 at Stage 1 in identifying Complete EHRs and/or EHR Modules that have been certified to the most current set of adopted certification criteria and therefore could be used to meet the definition of Certified EHR Technology.

Comments. Several commenters disagreed with our position that Complete EHRs and EHR Modules need to include the capabilities necessary to meet the most current set of certification criteria adopted by the Secretary at 45 CFR 170 subpart C in order to satisfy the definition of Certified EHR Technology. Other commenters agreed and contended that Certified EHR Technology should always be as up-to-date and as current as possible. Of those commenters that disagreed, their concerns focused on two areas: the validity/expiration of certified status; and the effect on eligible professionals and eligible hospitals who adopt Certified EHR Technology in the year before we anticipate updating adopted standards, implementation specifications, and certification criteria for a future stage of meaningful use.

Commenters asserted that some certification criteria were unlikely to change between meaningful use stages and that a Complete EHR or EHR Module's certification should remain valid and not expire until the Secretary has adopted updated certification criteria. These commenters requested that ONC only make changes to certification criteria on a cyclical basis and only when necessary for meaningful use or to advance interoperability.

A number of commenters expressed concerns about our position and contended that it would require eligible professionals and eligible hospitals who adopt Certified EHR Technology in 2012 (and attempt meaningful use Stage 1 in 2012) to upgrade their Certified EHR Technology twice in two years in order to continue to be eligible for meaningful use incentives during 2013 when they would still only have to meet meaningful use Stage 1 (according to the staggered approach for meaningful use stages that was proposed by CMS). Some of these commenters viewed this as a penalty and disagreed with our position that eligible professionals and eligible hospitals should be required to use Certified EHR Technology that had been certified to the most recently adopted certification criteria. Additionally, these commenters stated that it is not in the best interest of eligible professionals and eligible hospitals to require that they use Certified EHR Technology that includes more advanced capabilities than are necessary to qualify for the meaningful use stage that they are attempting to meet. Finally, one commenter requested that we offer a graphical depiction to more clearly convey our position.

Response. In the Temporary Certification Program final rule, we discussed the concept of validity as it relates to the definition of Certified EHR Technology and the certifications that are issued to Complete EHRs and EHR Modules. We believe it is necessary to clarify that discussion in this final rule. We explained that an eligible professional or eligible hospital cannot assert that a certification issued to a particular Complete EHR or EHR Module is valid for purposes of satisfying the definition of Certified EHR Technology if the certification criteria (including the standards and implementation specifications referenced by the criteria) that are related to a particular capability have been modified. In other words, if the applicable certification criteria have been altered or changed, then an eligible professional or eligible hospital can no longer represent that a certified Complete EHR or combination of certified EHR Modules continues to constitute Certified EHR Technology based on the certifications that were previously issued.

As mentioned in both the HIT Standards and Certification Criteria final rule and the Medicare and Medicaid EHR Incentive Programs final rule, it is anticipated that the requirements for meaningful use will be adjusted every two years. We expect the Secretary will adopt certification criteria through rulemaking every two years in correlation with the changes to the meaningful use requirements. We also recognize, however, that circumstances may necessitate a deviation from the expected two-year rulemaking cycle, such as with the interim final rule published on October 13, 2010 (75 FR 62686) to remove the previously adopted implementation specifications related to public health surveillance. Future rulemakings could potentially include the adoption of new and revised certification criteria in addition to those already adopted. We consider new certification criteria to be those that specify capabilities for which the Secretary has not previously adopted certification criteria. New certification criteria would also include certification criteria that were previously adopted for Complete EHRs or EHR Modules designed for a specific setting and are subsequently adopted for Complete EHRs or EHR Modules designed for a different setting (for example, if the Secretary previously adopted a certification criterion at § 170.304 only for Complete EHRs or EHR Modules designed for an ambulatory setting and then subsequently adopts that certification criterion at § 170.306 for Complete EHRs or EHR Modules designed for an inpatient setting). We consider revised certification criteria to be certification criteria previously adopted by the Secretary that are modified to add, remove, or otherwise alter the specified capabilities and/or the standard(s) or implementation specification(s) referred to by the

certification criteria. Revised certification criteria would also include certification criteria that were previously adopted as optional but are subsequently adopted as mandatory (for example, if the optional criterion at § 170.302(w) is subsequently adopted as a mandatory criterion).

Only when eligible professionals or eligible hospitals are in possession of a Complete EHR or EHR Module that has been certified to all of the applicable certification criteria, including new and revised certification criteria, that have been adopted by the Secretary at subpart C of part 170, will they be able to assert that they possess a Complete EHR or EHR Module with a certification that would be considered valid for purposes of satisfying the definition of Certified EHR Technology. For example, based on our expectation that the meaningful use requirements will be modified every two years, we anticipate that the Secretary will adopt certification criteria during 2012 for the 2013 and 2014 payment years of the Medicare and Medicaid EHR Incentive Programs (referenced in Table 1 below). A Complete EHR that was previously certified in 2010 to the certification criteria adopted for the 2011 and 2012 payment years must be certified again as compliant with all of the applicable certification criteria adopted for the 2013 and 2014 payment years in order for that Complete EHR to continue to meet the definition of Certified EHR Technology. As we discuss in the next section of this preamble (*P. Differential or Gap Certification*), the permanent certification program will include the option of "gap certification" in an effort to provide a more efficient and streamlined process for the certification of previously certified Complete EHRs and EHR Modules.

We explained in the HIT Standards and Certification Criteria final rule that additional flexibility and specificity can be introduced into future cycles of rulemaking through the adoption and designation of "optional" standards, implementation specifications, and certification criteria. We acknowledged that these would be voluntary and would not be required for testing and certifying a Complete EHR or EHR Module, although they could help to prepare the HIT industry for future mandatory certification requirements. Thus, in certain instances, the Secretary may adopt through rulemaking additional standards and/or implementation specifications that would be referenced as optional by a previously adopted certification criterion or criteria, in an effort to provide EHR technology developers more flexibility with respect to what is permitted to achieve certification for a Complete EHR or EHR Module. We emphasize that this would not affect the validity of certifications that were previously issued to Complete EHRs and EHR Modules. In other words, a previously certified Complete EHR or EHR Module would not be required to be certified according to new optional standard(s) or implementation specifications in order for it to continue to be used to meet the definition of Certified EHR Technology.

As we stated in the Proposed Rule, if a previously certified Complete EHR is not tested and certified as compliant with all of the applicable certification criteria adopted by the Secretary, it would not lose its certification, but it also would no longer satisfy the definition of Certified EHR Technology. Many commenters acknowledged that especially in situations where certification criteria have been adopted to improve the interoperability of EHR technology, certification to new and revised certification criteria would be needed and justified in order to meet the definition of Certified EHR Technology. With respect to the validity of a Complete EHR or EHR Module's certification, we ask commenters to consider how they would expect to meet the requirements of a subsequent stage of meaningful use without the technical capabilities necessary to do so. A Complete EHR or EHR Module's certification is only as good as the capabilities that can be associated with that certification. If the Secretary adopts new or revised certification criteria, Complete EHRs and likely many EHR Modules may no longer provide all of the capabilities that would be necessary to support an eligible professional's or eligible hospital's attempt to meet the requirements of a particular stage of meaningful use.

In its final rule, CMS indicated that "[t]he stages of criteria of meaningful use and how they are demonstrated are described further in this final rule and will be updated in subsequent rulemaking to reflect advances in HIT products and infrastructure. *We note that such future rulemaking might also include updates to the Stage 1 criteria*." 75 FR 44323 (emphasis added). We believe that the commenters who expressed concerns and objected to our discussion of the expiration/validity of a Complete EHR or EHR Module's certified status did not account for the possibility that the requirements for an eligible professional or eligible hospital to meet meaningful use Stage 1 in 2013 or 2014 could be different and possibly more demanding than they were for meaningful use Stage 1 in 2012. Contrary to some commenters' assumptions and consistent with the statement by CMS quoted above, it is possible that in a subsequent rulemaking to establish the objectives and measures for meaningful use Stage 2, CMS could change what is required to successfully demonstrate meaningful use Stage 1 in 2013. Consequently, such changes could include additional requirements that are based on advances in HIT and go beyond the requirements that have been finalized by CMS for meaningful use Stage 1 in 2011 and 2012. Therefore, an eligible professional or eligible hospital who demonstrates meaningful use for the first time in 2012 may potentially need Certified EHR Technology with new or additional capabilities in order to satisfy the meaningful use Stage 1 requirements in 2013.

Because the HITECH Act requires eligible professionals and eligible hospitals to use Certified EHR Technology in order to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs, we reaffirm our position expressed in the Proposed Rule. Regardless of the year and meaningful use stage at which eligible professionals or eligible hospitals enter the Medicare or Medicaid EHR Incentive Programs, they must use Certified EHR Technology that has been certified to all of the applicable certification criteria adopted by the Secretary at subpart C of part 170, which includes new and revised certification criteria that have been adopted since their EHR technology was previously certified. We believe this position takes into account the best interests of eligible professionals and eligible hospitals because those who implement EHR technology that meets the definition of Certified EHR Technology will have the assurance that their EHR technology includes the requisite capabilities to support their attempts to demonstrate meaningful use. Moreover, our position ensures that *all* Certified EHR Technology will have been tested and certified to the same standards and implementation specifications and provide the same level of interoperability, which would not be the case if we were to permit different variations of Certified EHR Technology to exist.

To further address concerns raised by the commenters, we clarify as we did in the Temporary Certification Program final rule that if the temporary certification program sunsets on December 31, 2011, and the permanent certification program is fully constituted at the start of 2012, Complete EHRs and

EHR Modules that were previously certified by ONC–ATCBs to the certification criteria adopted by the Secretary for the 2011/2012 payment years will not need to be recertified as having met the certification criteria for those years. In other words, the fact that the permanent certification program has replaced the temporary certification program will not automatically render certifications that were issued by ONC–ATCBs pursuant to the certification criteria adopted for the 2011/2012 payment years invalid for the purpose of meeting the definition of Certified EHR Technology. However, once the permanent certification program is fully constituted and after the Secretary has adopted new or revised certification criteria (which we expect will occur in 2012, based on the two-year rulemaking cycle), Complete EHRs and EHR Modules that were previously certified under the temporary certification program by ONC–ATCBs must be certified by an ONC–ACB.

We provide the following illustration overlaid on "Table 1—Stage of Meaningful Use Criteria by Payment Year" from theMedicare and Medicaid EHR Incentive Programs final rule (75 FR 44323) to more clearly convey the discussion above. This illustration would also be applicable to the Medicaid program.

TABLE 1—STAGE OF MEANINGFUL USE CRITERIA BY PAYMENT YEAR

First Payment Year	Payment Year			
	2011	2012	2013	2014
2011	Stage 1	Stage 1	Stage 2	Stage 2.
2012		Stage 1	Stage 1	Stage 2.
2013			Stage 1	Stage 1.
2014				Stage 1.
	Complete EHRs and EHR Modules certified by ONC–ATCBs or ONC–ACBs[2] to all of the applicable certification criteria adopted for the 2011 & 2012 payment years meet the definition of Certified EHR Technology.		Complete EHRs and EHR Modules certified by ONC–ACBs to all of the applicable certification criteria adopted for the 2013 & 2014 payment years meet the definition of Certified EHR Technology.	

Comments. In response to our question about how to identify those Complete EHRs and/or EHR Modules that have been certified to the most current set of adopted certification criteria (and thus would constitute Certified EHR Technology), several commenters offered suggestions regarding "labeling" conventions for Complete EHRs and EHR Modules. Overall, commenters indicated that specific "labeling" parameters would help clarify whether a Complete EHR or EHR Module's certification is current. These commenters offered a variety of suggested techniques, including identifying Complete EHRs and EHR Modules according to: the applicable meaningful use stage they could be used for; the month and year they had been certified; and the year associated with the most current set of adopted standards, implementation specifications, and certification criteria. Additionally, in light of the EHR Module "pre-coordinated, integrated bundle" concept we proposed with respect to the certification of EHR Modules to the adopted privacy and security certification criteria, one commenter recommended that we assign specific "labeling" constraints to certifications issued to pre-coordinated, integrated bundles of EHR Modules. Another comment suggested "labeling" constraints be assigned when a Complete EHR or EHR Module had been certified at an eligible professional or eligible hospital's site (*e.g.,* at the hospital where the Complete EHR is deployed).

Response. We agree with the commenters who requested more specific requirements surrounding how a Complete EHR or EHR Module's certified status should be represented and communicated. We believe more specificity will assist eligible professionals and eligible hospitals with their purchasing decisions by helping them to identify those Complete EHRs and EHR Modules that have a current and valid certification issued by an ONC–ACB. As previously discussed, the ONC–AA must verify that ONC–ACBs conform to Guide 65 at a minimum, which includes in section 14 a requirement that certification bodies (*i.e.,* ONC–ACBs) exercise control over the use and display of "certificates" and marks of conformity. To ensure consistency in how the certified status of a Complete EHR or EHR Module is represented and communicated, and in response to those comments, we are adding a new principle to the Principles of Proper Conduct for ONC–ACBs at § 170.523(k). We added a similar new Principle of Proper Conduct for ONC–ATCBs in the Temporary Certification Program final rule. The new Principle of Proper Conduct requires ONC–ACBs to ensure adherence to the following requirements when issuing a certification to Complete EHRs and/or EHR Modules:

(1) A Complete EHR or EHR Module developer must conspicuously include the following on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) "This [Complete EHR or EHR Module] is 20[XX]/20[XX] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments."; and

(ii) The information an ONC–ACB is required to report to the National Coordinator under paragraph (f) of this section for the specific Complete EHR or EHR Module at issue;

(2) A certification issued to a pre-coordinated, integrated bundle of EHR

[2] If the permanent certification program is fully constituted and the temporary certification program sunsets on December 31, 2011, all new requests made after that date for certification of Complete EHRs or EHR Modules to the 2011/2012 certification criteria will be processed by ONC–ACBs.

Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section except that the certification must also indicate each EHR Module that is included in the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

This new Principle of Proper Conduct is based on our assumption that the Secretary will adopt certification criteria through rulemaking every two years in correlation with the expected modifications to the meaningful use requirements. With respect to the requirement in § 170.523(k)(1)(i) regarding "20[XX]/20[XX] compliant," we expect ONC–ACBs will indicate the years "2011/2012 compliant" for all Complete EHRs and EHR Modules that are certified to the certification criteria adopted by the Secretary for the 2011 and 2012 payment years of the Medicare and Medicaid EHR Incentive Programs. Continuing our assumption of a two-year rulemaking cycle, we expect ONC–ACBs to follow this convention as the Secretary adopts certification criteria for subsequent payment years. For example, if the Secretary adopts certification criteria as expected in 2012 for the 2013 and 2014 payment years, ONC–ACBs would indicate "2013/2014 compliant."

Given the clarification we provided as to when a Complete EHR or EHR Module's certification will be considered valid for purposes of meeting the definition of Certified EHR Technology, we believe it would be inappropriate and misleading to adopt an identification requirement that is solely associated with the meaningful use stages. We also believe it would be inappropriate to identify a Complete EHR or EHR Module based on whether its certification could be attributed to a particular entity at a particular location. While unlikely, we do not want to presume that such a certified Complete EHR or EHR Module would not be useful to another eligible professional or eligible hospital.

We do, however, agree with the commenter who suggested the specific constraint for a pre-coordinated, integrated bundle of EHR Modules. As we explained, we would expect that EHR Module developer(s) will have addressed any issues related to the compatibility of EHR Modules that make up a pre-coordinated, integrated bundle before the bundle is presented for certification pursuant to § 170.550(e)(1). The pre-coordinated, integrated bundle of EHR Modules is greater than the sum of the individual EHR Modules that make up the bundle, and for that reason, we clarify that individual EHR Modules that are certified as part of a pre-coordinated, integrated bundle would not each separately inherit a certification just because they had been certified as part of a bundle. For example, if EHR Modules A, B, C, and D are certified as a pre-coordinated, integrated bundle, EHR Module C would not on its own be certified just by virtue of the fact that it was part of a certified pre-coordinated, integrated bundle. If an EHR Module developer wanted to make EHR Module C available for use by eligible professionals and eligible hospitals as a single certified EHR Module independent of and separate from the bundle, then it must have EHR Module C separately certified by an ONC–ACB.

As we discussed in the Proposed Rule, there may be situations where the measures associated with a meaningful use objective may change as a result of subsequent rulemaking, but the capability a certified EHR Module would need to provide would not change. As a hypothetical example, during the expected 2012 rulemaking cycle, the threshold of the meaningful use Stage 1 measure associated with the "record patient demographics" objective could be increased from 50% to 75%. When the Secretary adopts certification criteria for the 2013/2014 payment years, however, the certification criterion or criteria that are applicable to an EHR Module designed to record patient demographics could potentially remain unchanged.

We recognize it may not be practical or beneficial for the EHR Module in this example to be certified again, where the certification criterion or criteria to which it was previously certified have not been revised and no new certification criteria have been adopted that are applicable to it. However, in accordance with § 170.423(k)(1) or § 170.523(k)(1), the ONC–ATCB or ONC–ACB that certified the EHR Module would have required the EHR Module developer to include certain information on its Web site and in other materials related to the payment years associated with the certification criteria to which the EHR Module was previously certified. To ensure that the information required by § 170.523(k)(1)(i) remains accurate and reflects the correct payment years, we will permit ONC–ACBs to provide updated certifications to previously certified EHR Modules.

We define "providing or provide an updated certification" as the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the EHR Module was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module. To verify that the certification criterion or criteria have not been revised, an ONC–ACB would compare the certification criterion or criteria to which the EHR Module was previously certified with all of the certification criteria adopted by the Secretary for the relevant payment years (in the example above, the 2013/2014 payment years). To verify whether new certification criteria adopted for privacy and security are applicable to the EHR Module, an ONC–ACB would complete the analysis described in § 170.550(e)(2) to determine, upon a request to provide an updated certification, whether the EHR Module developer has demonstrated and provided documentation that such certification criteria are inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criteria.

We believe that providing updated certifications is a pragmatic approach for the treatment of previously certified EHR Modules and that it is consistent with requirements specified in Guide 65, section 12 (Decision on certification), which requires certification bodies to issue certifications specifying the scope of the certification, the effective date of the certification, and any applicable terms. We also believe that this approach is consistent with Guide 65, section 14 (Use of licenses, certificates and marks of conformity), which requires the certification body to exercise proper control over the use and display of certificates and marks of conformity, including addressing incorrect references to the certification system or misleading use of certificates or marks. The information required by § 170.523(k)(1) is intended to assist eligible professionals and eligible hospitals in identifying specific EHR technology that could be purchased and adopted for the purpose of meeting the definition of Certified EHR Technology and attempting to demonstrate meaningful use. ONC–ACBs must be able to ensure that this information is kept current and accurate if it is to be

helpful to prospective purchasers of EHR technology and to instill confidence in the certifications issued under the permanent certification program. We are defining "providing or provide an updated certification" in § 170.502 and are adding a new provision to § 170.550, designated as paragraph (d), to permit ONC–ACBs to provide updated certifications to previously certified EHR Module(s).

ONC–ACBs may choose to provide updated certifications but are not required to do so, because we recognize situations could exist where an ONC–ACB is not comfortable providing an updated certification. For instance, an ONC–ACB may not want to provide an updated certification if it did not issue the original certification to the EHR Module or if there has been an extended period of time since the EHR Module was tested and/or certified. If an ONC–ACB elects not to provide updated certifications, an EHR Module developer may choose to have its EHR Module recertified and/or retested, even though the certification criterion or criteria to which the EHR Module was previously certified have not been revised and no new certification criteria have been adopted that are applicable to the EHR Module. In order to make the certification process as efficient as possible in this scenario, we will permit ONC–ACBs to rely on prior testing completed by an ONC–ATCB. Accordingly, we are revising § 170.523(h) to permit ONC–ACBs to rely on the results of testing performed by ONC–ATCBs for the purpose of certifying a previously certified EHR Module(s) if the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and no new certification criteria are applicable to the EHR Module(s).

Comments. Several commenters requested that we clarify whether each updated version of a Complete EHR or EHR Module would need to be recertified in order for its certification to remain valid, and whether there would be a mechanism available to accommodate routine changes and product maintenance without the need for full recertification of each updated version of a previously certified Complete EHR or EHR Module. Some of these commenters stressed that they provide bug-fixes and other maintenance upgrades to customers on a regular basis and that those versions are normally denoted by a new "dot release" (*e.g.,* version 7.1.1 when 7.1 received certification). Another commenter requested that we consider the impact of potentially more dynamic software development/release models, such as those related to cloud computing and software-as-a-service, that may not fit a traditional (major/minor/maintenance) release schedule. The commenter indicated that there may be more frequent software updates for these types of EHR technologies.

Response. We understand that Complete EHR and EHR Module developers will conduct routine maintenance. We also recognize that at times Complete EHR and EHR Module developers will provide new or modified capabilities either to make the Complete EHR or EHR Module perform more efficiently and/or to improve user experiences related to certain functionality (*e.g.,* a new graphical user interface (GUI)). Our main concern is whether these changes adversely affect the capabilities of a Complete EHR or EHR Module that has already been certified and whether the changes are such that the Complete EHR or EHR Module would no longer support an eligible professional or eligible hospital's achievement of meaningful use. Accordingly, we clarify that a previously certified Complete EHR or EHR Module may be updated for routine maintenance or to include new or modified capabilities without the need for recertification, and such changes may affect capabilities that are related or unrelated to the certification criteria adopted by the Secretary.[3] However, we do not believe that it would be wise to simply permit a Complete EHR or EHR Module developer to claim without any verification that the routine maintenance or new/modified capabilities included in a newer version do not adversely affect the proper functioning of the capabilities for which certification was previously granted. An ONC–ACB should, at a minimum, review an attestation submitted by a Complete EHR or EHR Module developer explaining the changes that were made and the reasons for those changes, as well as other information and supporting documentation that would be necessary for the ONC–ACB to evaluate the potential effects of the changes on previously certified capabilities. We believe this process is consistent with the requirements placed on certification bodies by Guide 65, sections 4.6.2 (related to conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification) and 12.4 (related to decisions on certifications).

As a result, we are adding a new provision to § 170.545, designated as paragraph (d), that requires an ONC–ACB to accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified. We are also adding a similar provision to § 170.550, designated as paragraph (f), that requires an ONC–ACB to accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified. However, consistent with both of these new provisions, the developer of the Complete EHR or EHR Module(s), must submit an attestation as described above in the form and format specified by the ONC–ACB that the newer version does not adversely affect any capabilities for which certification criteria have been adopted. After reviewing the attestation, the ONC–ACB must determine whether the Complete EHR's or EHR Module's capabilities, for which certification criteria have been adopted, have been adversely affected (which would consequently require the newer version to be recertified), or whether to grant a certification to the newer version of the previously certified Complete EHR or EHR Module that is based on the previous certification. In determining whether the newer version should be recertified, the ONC–ACB may also determine whether retesting is necessary.

If the ONC–ACB issues a certification to a newer version of a previously certified Complete EHR or EHR Module, the ONC–ACB must include this certification in its weekly report to the National Coordinator. We believe that for the purposes of associating a certification with a given EHR technology, this policy is appropriate regardless of the software development/release approach employed by an EHR technology developer. As we have stated before, certification represents a snapshot, a fixed point in time, where it has been confirmed (in this case by an ONC–ACB) that a Complete EHR or EHR Module has met all applicable certification criteria adopted by the Secretary. Thus, if a different version of a Complete EHR or EHR Module is made available and the EHR technology

[3] We understand that Complete EHR and EHR Module developers typically consider a "minor version release" to be, for example, a version number change from 3.0 to 3.1 and consider a "major version release" to be, for example, a version number change from 4.0 to 5.0. In providing for this flexibility, we do not presume the version numbering schema that a Complete EHR or EHR Module developer may choose to utilize. As a result, we do not preclude a Complete EHR or EHR Module developer from submitting an attestation to an ONC–ACB for a Complete EHR or EHR Module whose version number may represent a minor or major version change.

developer seeks to have this version inherit a prior version's certification, the prior version's certification needs to be formally associated with this newer version and subsequently reported to the National Coordinator. Without this association, an EHR technology developer would not be able to assert that the updated or modified EHR technology was "certified," nor would eligible professionals or eligible hospitals be able to verify on ONC's Certified HIT Products List (CHPL) that the EHR technology is certified.

Aside from the requirements discussed above, we do not specify the fees or any other processes that an ONC–ACB must follow before granting certified status to a newer version of a previously certified Complete EHR or EHR Module based on the submitted attestation. We encourage ONC–ACBs to develop streamlined approaches for attestations in order to accommodate different software release models and schedules.

P. Differential or Gap Certification

We stated in the Proposed Rule that, after Complete EHRs and EHR Modules have been certified as being in compliance with the certification criteria associated with meaningful use Stage 1, it may benefit both Complete EHR and EHR Module developers as well as eligible professionals and eligible hospitals if some form of differential certification were available. We described differential certification as the certification of Complete EHRs and/or EHR Modules to the differences between the certification criteria adopted by the Secretary associated with one stage of meaningful use and a subsequent stage of meaningful use. As an example, we stated that if the Secretary were to adopt 5 new certification criteria to support meaningful use Stage 2 and those were the only additional capabilities that needed to be certified in order for a Complete EHR's certification to be valid again (*i.e.,* all other certification criteria remained the same) for the purposes of meaningful use Stage 2, then the Complete EHR would only have to be tested and certified to those 5 criteria rather than the entire set of certification criteria again.

We noted that differential certification could be a valuable and pragmatic approach for the future and that it may further reduce costs for certification and expedite the certification process. Accordingly, we requested public comments on whether we should require ONC–ACBs to offer differential certification, what factors we should consider in determining when differential certification would be appropriate and when it would not, and when differential certification should begin. To further clarify these requests and inform commenters, we noted the factors we thought were appropriate for consideration in determining when to allow for differential certification. These factors included whether the standard(s) associated with a certification criterion or criteria changed and whether additional certification criteria changed in such a way that they affected other previously certified capabilities of a Complete EHR or EHR Module. We specifically asked whether differential certification should be permitted to begin with Complete EHRs and EHR Modules certified under the temporary certification program (*i.e.,* the differences between 2011 and 2013) or after all Complete EHRs and EHR Modules had been certified once under the permanent certification program (*i.e.,* the differences between 2013 and 2015). Regarding these options, we asked commenters to consider the differences in rigor that we expect Complete EHRs and EHR Modules will go through to get certified under the permanent certification program.

Comments. Commenters overwhelmingly supported some form of differential certification based on, as we noted, the potential for efficiencies and lower certification costs. These commenters expressed general agreement with the factors we specified for determining when differential certification would be appropriate. That is, they stated that testing and certifying a Complete EHR or EHR Module to only new or revised certification criteria would be appropriate as long as other required capabilities (as specified in other adopted certification criteria) of a Complete EHR or other EHR Modules were not also affected by the new or revised certification criteria. Conversely, a few commenters did not believe that differential certification would be appropriate based on various concerns. One commenter suggested that testing to only new or revised certification criteria could be time consuming and cost prohibitive. Another commenter contended that differential certification will create "tiers" in the market of fully certified versus differentially certified Complete EHRs and EHR Modules, which could lead to confusion among purchasers. A couple of commenters expressed concern about ONC–ACBs guaranteeing the compliance of all capabilities required by adopted certification criteria of a Complete EHR without testing all of the components. A couple of commenters also noted that if differential certification is allowed, ONC–ACBs should not be required to offer it as an option for certification. Rather, it should be up to each ONC–ACB to decide whether to conduct differential certification.

Commenters who were in favor of differential certification indicated strong support for beginning differential certification with the differences between the 2011 and 2013 certification criteria adopted by the Secretary. These commenters reasoned that the potential for lower certification costs and reduced certification times should be made available to the market as soon as possible, particularly if the separate testing and certification processes of the permanent certification program could increase the time for certified Complete EHRs and EHR Modules to reach the market. Alternatively, a few commenters stated that it would be more appropriate for Complete EHRs and EHR Modules to be tested and certified at least once under the proposed more rigorous permanent certification program before they would be considered eligible for differential certification.

Response. We understand based on our research that the term "gap certification" is commonly used by the HIT industry to refer to the concept we have described as "differential certification." As a result, for consistency and ease of reference, we will use the term "gap certification" instead of "differential certification" for purposes of the permanent certification program. The description of "differential certification" that we gave in the Proposed Rule focused on the differences between adopted certification criteria as related to the stages of meaningful use. As noted earlier in this final rule, however, the Medicare and Medicaid EHR Incentive Programs final rule indicated that the meaningful use Stage 1 requirements may be updated in future rulemaking, such as when the requirements for Stage 2 are established. As a result, the concept of gap certification must allow for the possibility that the Secretary may adopt certification criteria through future rulemaking that would encompass and be associated with both the revised Stage 1 requirements and newly established Stage 2 requirements. This possibility is consistent with our position that, regardless of the year and meaningful use stage at which an eligible professional or eligible hospital enters the Medicare or Medicaid EHR Incentive Programs, they must use Certified EHR Technology that has been certified to all of the applicable certification criteria adopted by the Secretary at subpart C of part 170. Thus,

gap certification must focus on the differences between certification criteria that are adopted through rulemaking at different points in time rather than the differences between the stages of meaningful use.

We define and will use the term gap certification to mean the certification of a previously certified Complete EHR or EHR Module to: (1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and (2) all other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used previously to certify the Complete EHR or EHR Module. We believe this definition of gap certification is conceptually analogous to the description of differential certification in the Proposed Rule as well as common industry usage of the term.

While a commenter asserted that testing to only new or revised certification criteria could be more time consuming and cost prohibitive, commenters overwhelmingly agreed with our premise that gap certification would likely be a less costly and time-consuming certification option for Complete EHR and EHR Module developers. Further, we believe that the potential lower costs and expedited certification timeframes that gap certification will presumably offer outweigh the concerns some commenters raised about the reliability of testing under the temporary certification program. As previously stated in this final rule, the testing and certification performed under the temporary certification program is conducted by testing and certification bodies that are determined to be qualified and have been authorized by the National Coordinator. Complete EHRs and EHR Modules are tested by ONC–ATCBs using test tools and test procedures approved by the National Coordinator and should be expected to perform consistent with their certifications. Therefore, ONC–ACBs should be confident in relying upon the test results provided by ONC–ATCBs when performing gap certification under the permanent certification program. Accordingly, gap certification will be available as an option for ONC–ACBs to offer as soon as ONC–ACBs are authorized to begin performing certifications under the permanent certification program.

A few commenters suggested that gap certification would lead to "tiers" in the market of "fully tested and certified" Complete EHRs and EHR Modules and "partially tested and certified" Complete EHRs and EHR Modules, while a couple of other commenters expressed concern about ONC–ACBs guaranteeing the compliance of all capabilities of a Complete EHR without testing all of the components. We believe, as suggested by commenters, that the decision on whether to conduct gap certification is best left to each ONC–ACB. However, as discussed above, we believe that the testing performed by ONC–ATCBs or by any NVLAP-accredited testing laboratory will be valid and reliable. Therefore, when gap certifying a Complete EHR or EHR Module, an ONC–ACB will be expected to issue a certification for the entire Complete EHR or EHR Module that it gap certifies. For these reasons, the HIT market should consider a Complete EHR or EHR Module that has been gap certified to be equal to a Complete EHR or EHR Module that has been fully tested and certified to all applicable certification criteria adopted by the Secretary. In addition, as discussed earlier in this preamble, ONC–ACBs will be expected to conduct annual surveillance of the Complete EHRs and/or EHR Modules that they certify under the permanent certification program. Surveillance should provide additional assurances to the HIT market that Complete EHRs and EHR Modules will continue to perform in an operational setting or "live" environment as they did when they were certified.

Consistent with this discussion, we are adding the definition of gap certification to § 170.502 and adding new provisions to § 170.545 (paragraph (c)) and § 170.550 (paragraph (c)) to permit ONC–ACBs to provide the option of and to perform gap certification under the permanent certification program. In addition to these revisions, we are revising § 170.523(h) to permit ONC–ACBs to accept the results of testing performed on Complete EHRs and EHR Modules by ONC–ATCBs under the temporary certification program for the purpose of gap certification. These testing results may be necessary for conducting gap certification under the permanent certification program when previously certified Complete EHRs and EHR Modules were last tested under the temporary certification program.

Q. Barriers to Entry for Potential ONC–ACBs and an ONC–Managed Certification Process

We noted in the Proposed Rule that the overall success of the Medicare and Medicaid EHR Incentive Programs could be jeopardized if the certification program for EHR technology fails to operate properly. We requested public comment on specific issues related to the proposed permanent certification program that could adversely affect the operation of that program. First, we asked whether the proposed provisions of the permanent certification program created high barriers to market entry for potential ONC–ACBs and, if so, how we could revise the proposed requirements to lower those barriers and encourage participation. Second, we expressed concern about the potential risks to the permanent certification program if no ONC–ACBs were authorized or only one ONC–ACB was authorized and engaged in monopolistic behavior. We requested public comment on potential approaches that could be pursued to stimulate market involvement or remedy these situations if they were to develop, including the possibility of the National Coordinator establishing a temporary ONC-managed certification process that would include some type of certification review board. We noted that this option was not preferred and would come with significant limitations. In particular, section 3001(c)(5) of the PHSA does not expressly authorize the National Coordinator or the Secretary to assess and collect fees related to the certification of HIT and subsequently retain and use those fees to administer an ONC-managed certification process if it were established.

Comments. Commenters stated that the proposed provisions of the permanent certification program did not present high barriers to entry for potential ONC–ACBs. Commenters also generally agreed that we should eliminate any identified barriers to entry with one commenter specifically suggesting that the National Coordinator could waive certain conditions that are creating barriers to entry as long as it would not adversely impact patient safety or quality of care. Another commenter noted that the proposed permanent certification program permits multiple entry points for organizations to pursue ONC–ACB status, allowing the market to decide how many ONC–ACBs are acceptable.

Most commenters expressed agreement with our proposal for a temporary ONC-managed certification process to stimulate market involvement or remedy the situations described above and in the Proposed Rule. Some commenters suggested that if there were fewer than two ONC–ACBs at the start of the permanent certification program we should continue the temporary certification program or allow ONC–ATCBs in good standing under the temporary certification program to

become ONC–ACBs under the permanent certification program without having to meet any of the application requirements of the permanent certification program. Another commenter suggested that if these options were not immediately viable then we should allow for self-attestation by Complete EHR and EHR Module developers to the certification criteria until there are a sufficient number of ONC–ACBs. Conversely, some commenters contended that if there was only one ONC–ACB it would not necessarily be the result of the permanent certification program requirements. Although these commenters stated that the authorization of more than one ONC–ACB would be preferable to handle requests for certification, they asserted that one ONC–ACB could be a good starting point for the permanent certification program, at least until other ONC–ACBs became operational. A commenter reasoned that the accreditation guidelines that ONC–ACBs must adhere to should be sufficient to preclude a single ONC–ACB from acting in a monopolistic or other improper manner.

Response. We agree with many of the sentiments expressed by the commenters. We agree that there are multiple entry points for qualified organizations who seek to become ONC–ACBs, such as applying to become an ONC–ACB for only Complete EHRs, only EHR Modules, or only limited types of EHR Modules. We also agree that the market will likely determine the appropriate number of ONC–ACBs and that only one ONC–ACB may be sufficient for starting (and potentially operating long term) the permanent certification program. For comparison, consistent with our estimate, there are currently 5 ONC–ATCBs under the temporary certification program. We acknowledge, however, that there remains the remote possibility that there may be no ONC–ACBs under the permanent certification program, that one ONC–ACB will not be sufficient to meet demand, or that only one ONC–ACB will be authorized and could engage in conduct that is detrimental to the permanent certification program.

To begin the permanent certification program, we believe that we have established an approach that addresses the concerns expressed by some commenters and is consistent with the solutions they offered. Section 170.490 provides that the temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. We stated in the Temporary Certification Program final rule that in determining whether the permanent certification program is fully constituted, the National Coordinator would consider whether there are a sufficient number of ONC–ACBs and accredited testing laboratories to address the current market demand. We believe this approach will ensure that the permanent certification program functions properly at the outset. If we determine at a later time under the permanent certification program that an insufficient number of ONC–ACBs exists, we will consider what steps may be taken to remedy the situation. This may include implementing a temporary ONC-managed certification process and/or evaluating other means for stimulating the market, such as revising or waiving certain ONC–ACB requirements or taking other actions as suggested by the commenters.

R. General Comments

We received comments that were not attributable to a specific provision of the permanent certification program, but were still reasonably within the scope of the program. These comments addressed the timing of the permanent certification program; "grandfathering" of previously certified technology; the potential for a backlog of requests for certification; the costs of certification; and the safety of Complete EHRs, EHR Modules and other types of HIT.

Comments. Although we did not propose or discuss the concept of "grandfathering" in the Proposed Rule, several commenters made recommendations on the subject. To summarize the discussion of comments in the Temporary Certification Program final rule, in general, the concept of grandfathering would allow technology that had been certified prior to the inception of the temporary and/or permanent certification programs to be deemed Certified EHR Technology.

Response. In the Temporary Certification Program final rule, we responded to comments on the concept of grandfathering and concluded that any form of grandfathering would be inappropriate for purposes of our certification programs and inconsistent with the statutory requirements for Certified EHR Technology set forth in the PHSA. 75 FR 36186–36187. Our position on grandfathering as stated in the Temporary Certification Program final rule remains valid.

Comments. Commenters requested that we take action to prevent testing and certification monopolies and backlogs of requests for testing and certification. Commenters also requested that we mandate pricing for certification or at least establish a reasonable fee requirement.

Response. We believe that through the policies we have established in this final rule, the permanent certification program is inclusive of as many potential applicants for ONC–ACB status as possible, and that we have created an environment that is likely to result in multiple ONC–ACBs. Further, we believe that multiple ONC–ACBs and market dynamics, particularly competition, will address the commenters' concerns about potential monopolies, appropriate costs for certification, and the timely and efficient processing of requests for the certification of Complete EHRs and EHR Modules. Accreditation will require that potential ONC–ACBs comply with Guide 65, which requires certification bodies to make their services accessible to all applicants whose activities fall within its declared field of operation (*i.e.,* the permanent certification program), including not having any undue financial or other conditions. As noted throughout this rule, an ONC–ACB must maintain its accreditation to remain in good standing under the permanent certification program.

Comments. A commenter requested that the National Coordinator establish a single application process for the testing and certification of developers' HIT. By doing so, the commenter contended that this would alert accredited testing laboratories and ONC–ACBs of a developer's readiness and intent to apply for testing and/or certification.

Response. We do not believe it is necessary or appropriate to create such an "application process." Each accredited testing laboratory and ONC–ACB is capable of establishing their own customer base based on a multitude of factors including pricing, efficiency, services offered, and prior relationships. Further, we assume that a HIT developer's readiness and "intent" to apply may fluctuate based on multiple factors, including whether their Complete EHR and/or EHR Module successfully passed testing or whether they determine testing and/or certification of their HIT should be delayed. Accordingly, we believe it is appropriate for each accredited testing laboratory and ONC–ACB to establish its own process for soliciting and accepting requests for testing and certification, as applicable.

Comments. A few commenters expressed concern over the potential safety risks that could be associated with poorly planned, implemented, and

used EHR technology and suggested that patient safety should be considered in the development and implementation of the permanent certification program.

Response. We understand and are acutely aware of the concerns expressed by the commenters regarding patient health and safety. We believe that the permanent certification program has been sufficiently constituted to ensure that ONC–ACBs will competently certify Complete EHRs, EHR Modules and potentially other types of HIT. We have established a process in the permanent certification program that the National Coordinator could use to immediately suspend an ONC–ACB's authority to issue certifications if there is reliable evidence indicating that allowing the ONC–ACB to continue issuing certifications would pose an adverse risk to patient health and safety. The permanent certification program also includes a post-market surveillance program that is designed to ensure that certified Complete EHRs and EHR Modules perform in the market as certified and may also shed light on any safety concerns reported by eligible professionals and eligible hospitals.

S. Comments Beyond the Scope of This Final Rule

In response to the Proposed Rule, some commenters chose to raise issues that are beyond the scope of our proposals. We do not summarize or respond to those comments in this final rule. However, we will review the comments and consider whether other actions may be necessary, such as addressing the comments in later rulemakings or through guidance clarifying program operating procedures, based on the information or suggestions in the comments.

IV. Provisions of the Final Regulation

For the most part, this final rule incorporates the provisions of the Proposed Rule. Those provisions of this final rule that differ from the Proposed Rule are as follows:

• In § 170.501, we added language, based on our proposal and public comments, that expands the scope of the permanent certification program to "other types of HIT." We also added "the requirements that ONC–ACBs must follow to maintain their status" to properly identify that this subpart contains requirements that ONC–ACBs must follow to maintain their status under the permanent certification program.

• In § 170.502, we revised the definition of applicant by removing the condition that an applicant must "request" an application. We revised the definition of ONC–ACB by removing "at a minimum" from the definition to allow an organization or consortium of organizations to become an ONC–ACB that is authorized to certify only types of HIT besides Complete EHRs and/or EHR Modules. We also revised this definition by replacing "using the applicable certification criteria adopted by the Secretary" with "under the permanent certification program." In addition to revising the definitions of applicant and ONC–ACB, we added the definitions of "deployment site," "development site," "gap certification," "providing or provide an updated certification," and "remote certification" to this section.

• In § 170.503, we revised paragraph (b) to provide for a 30-day time period in which all interested accredited organizations may submit requests for ONC–AA status. We revised (b)(2) to specify that a request for ONC–AA status must include a detailed description of how the accreditation organization will ensure that the surveillance approaches used by ONC–ACBs include the use of consistent, objective, valid, and reliable methods. We revised paragraph (c) to permit the National Coordinator up to 60 days to review all timely submissions and determine which accreditation organization is best qualified to serve as the ONC–AA. We revised paragraph (c) to provide for the selection of an ONC–AA on a preliminary basis and subject to the resolution of the reconsideration process in § 170.504. We included in paragraph (c) the option, originally specified in proposed paragraph (d), for an accreditation organization to request reconsideration of the National Coordinator's decision to deny an accreditation organization ONC–AA status. We established a new provision, designated as paragraph (d), that specifies the final approval process for ONC–AA status. We revised paragraph (e)(2) to require an ONC–AA, in accrediting certification bodies, to ensure that surveillance approaches include the use of consistent, objective, valid and reliable methods. We revised paragraph (e)(4) to state that the ONC–AA will be required to review ONC–ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC–ACBs "with the conditions of their respective accreditations." We revised paragraph (f) to specify that an accreditation organization has not been granted ONC–AA status unless and until it is notified by the National Coordinator that it has been approved as the ONC–AA on a final basis pursuant to paragraph (d) of this section. We also revised paragraph (f) to specify that the National Coordinator will accept requests for ONC–AA status, in accordance with paragraph (b), at least 180 days before the then current ONC–AA's status is set to expire.

• In § 170.504, consistent with our revisions to § 170.503, we revised paragraph (a) to state that an accreditation organization that submits a timely request for ONC–AA status in accordance with § 170.503 and is denied may ask the National Coordinator to reconsider the decision to deny its request for ONC–AA status. We revised paragraph (b) to state that the accreditation organization's request for reconsideration must demonstrate that clear, factual errors were made in the review of its request for ONC–AA status and that the accreditation organization would have been selected as the ONC–AA pursuant to § 170.503(c) if those errors had been corrected. We revised paragraph (c) to permit the National Coordinator up to 30 days to review all timely received reconsideration requests and determine whether an accreditation organization has met the standard specified in paragraph (b) of this section. We revised paragraph (d) to state that if the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC–AA on a final basis and all other accreditation organizations will be notified that their requests for reconsideration have been denied.

• In § 170.505, we revised paragraph (b) by adding "or ONC–ACB" to clarify that either an applicant for ONC–ACB status or an ONC–ACB may, when necessary, utilize the specified correspondence methods. We also revised this section to apply its correspondence requirements to accreditation organizations that submit requests for ONC–AA status and the ONC–AA.

• In § 170.520, we revised paragraph (c) such that the documentation provided by the applicant must confirm that the applicant has been accredited by "the ONC–AA," instead of "an ONC–AA" as proposed.

• In § 170.523, we revised paragraph (e) by clarifying that site visits will be conducted during normal business hours. We revised paragraph (f) by replacing "vendor" with "Complete EHR or EHR Module developer." We also revised paragraph (f) by specifying that an ONC–ACB will be required to additionally report the clinical quality measures to which a Complete EHR or

EHR Module has been certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary. We revised paragraph (h) to require ONC–ACBs to only certify HIT, including Complete EHRs and/or EHR Module(s), that has been tested by a NVLAP-accredited testing laboratory using test tools and test procedures that have been approved by the National Coordinator. We also revised paragraph (h) to allow ONC–ACBs, under certain circumstances, to rely on testing that has been performed by ONC–ATCBs, which must also have been done using test tools and test procedures that have been approved by the National Coordinator. We revised paragraph (j) to clarify that an ONC–ACB will only be responsible for issuing refunds in situations where the ONC–ACB's conduct caused certification to be suspended and a request for certification is withdrawn, and in instances where the ONC–ACB's conduct caused the certification not to be completed or necessitated the recertification of Complete EHRs and/or EHR Module(s) that had been previously certified. Lastly, we added a new Principle of Proper Conduct for ONC–ACBs and designated it as paragraph (k). The new Principle of Proper Conduct will require ONC–ACBs to ensure that all Complete EHRs and EHR Modules are properly identified and marketed.

- In § 170.525, we revised paragraph (b) by removing "during the existence of the permanent certification program."
- In § 170.530, in response to public comment, we revised paragraph (b)(1) by removing the terms "inadvertent" and "minor." We revised paragraph (c)(1), also in response to public comment, to allow an applicant for ONC–ACB status to request an extension of the 15-day period provided to submit a revised application in response to a deficiency notice. We revised paragraph (c)(2) to state that the National Coordinator can grant an applicant's request for an extension of the 15-day period based on a finding of good cause. We revised paragraph (c)(3) to permit the National Coordinator to request clarification of statements and the correction of errors or omissions in a revised application during the 15-day period that the National Coordinator has to review a revised application. Finally, we revised paragraph (c)(4) to state that a denial notice issued to an applicant will indicate that the applicant cannot reapply for ONC–ACB status for a period of six months from the date of the denial notice.
- In § 170.540, we revised paragraph (b) to state, in relevant part, "Each ONC–ACB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program." We clarified in paragraph (c) that an ONC–ACB must include any updates to the information required to be provided under § 170.520 when requesting to have its status renewed. We also revised paragraph (c) to state that an ONC–ACB will need to have its status renewed every three years instead of every two years. We similarly revised paragraph (d) to state that an ONC–ACB's status will expire three years from the date it was granted by the National Coordinator unless it is renewed.
- In § 170.545, we revised paragraph (a) to state that "When certifying Complete EHRs, an ONC–ACB must certify Complete EHRs in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part." We redesignated proposed paragraph (b) as paragraph (e). We added three new provisions. We added a new provision, designated as paragraph (b), which states that an ONC–ACB must provide the option for a Complete EHR to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We added a new provision, designated as paragraph (c), to permit ONC–ACBs to provide the option for and perform gap certification. Finally, we added a new provision, designated as paragraph (d), which requires an ONC–ACB to accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified.
- In § 170.550, we removed proposed paragraphs (b) and (d) because they were redundant of other regulatory requirements within this subpart. We redesignated proposed paragraph (c) as paragraph (e) and revised it to state that EHR Modules shall be certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is presented for certification in one of the following manners: (1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or (2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion. We added four new provisions. We added a new provision, designated as paragraph (b), which states that an ONC–ACB must provide the option for an EHR Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part. We added a new provision, designated as paragraph (c), to permit ONC–ACBs to provide the option for and perform gap certification. We added a new provision, designated as paragraph (d), which permits an ONC–ACB to provide an updated certification to a previously certified EHR Module(s). Finally, we added a new provision, designated as paragraph (f), which requires an ONC–ACB to accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified.
- In § 170.555, we removed inadvertent references to testing under the permanent certification program.
- In § 170.557, we revised the section to require that an ONC–ACB provide remote certification for both development and deployment sites.
- In § 170.565, we revised paragraph (c)(1) to state that "[t]he National Coordinator may propose to revoke an ONC–ACB's status if the National Coordinator has reliable evidence that the ONC–ACB committed a Type-1 violation." The term "reliable" was inadvertently left out of the Proposed Rule. We also established a new provision. We designated this provision as paragraph (d) and redesignated proposed paragraphs (d) through (g) as paragraphs (e) through (h), respectively. Paragraph (d) provides the National Coordinator with the discretion to suspend an ONC–ACB's operations if there is reliable evidence indicating that the ONC–ACB has committed a Type-1 or Type-2 violation and that the continued certification of Complete EHRs, EHR Modules and/or other types of HIT by the ONC–ACB could have an adverse impact on patient health or safety. An ONC–ACB will have 3 days to respond to a notice of proposed suspension by explaining in writing why its operations should not be suspended. The National Coordinator

will be permitted up to 5 days to review the response and issue a determination to the ONC–ACB. The National Coordinator will make a determination to either rescind the proposed suspension, suspend the ONC–ACB until it has adequately corrected a Type-2 violation, or propose revocation in accordance with § 170.565(c) and suspend the ONC–ACB's operations for the duration of the revocation process. The National Coordinator may also make any one of the above determinations if an ONC–ACB fails to submit a timely response to a notice of proposed suspension. A suspension will become effective upon an ONC–ACB's receipt of a notice of suspension.

- We added § 170.599 to incorporate by reference ISO 17011 and Guide 65.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment on a proposed collection of information before it is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;
2. The accuracy of the agency's estimate of the information collection burden;
3. The quality, utility, and clarity of the information to be collected; and
4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In the Proposed Rule, we solicited public comment on each of these issues for the information collections set forth in 45 CFR §§ 170.503(b), 170.520, and 170.523(f) and (g). The final rule also specifies another information collection requirement pertaining to the annual submission by an ONC–ACB of a surveillance plan and surveillance results to the National Coordinator as required by § 170.523(i). The information collection requirement of § 170.523(i) was not specifically identified in the Proposed Rule, but was available for comment during the 60-day public comment period for the Proposed Rule and included in our request to OMB. Please refer to section E below for this information collection.

A. Collection of Information: Required Documentation for Requesting ONC–Approved Accreditor Status Under the Permanent Certification Program

Section 170.503(b) requires an accreditation organization to submit specific information to the National Coordinator to be considered for ONC–AA status under the permanent certification program. We estimated in the Proposed Rule that there will only be two accreditation organizations that will prepare and submit the information sought by the National Coordinator to be considered for ONC–AA status. We also provided estimates for the amount of time we believe will be necessary to collect and provide the information requested by the National Coordinator in § 170.503(b). Specifically, we estimated that it will take approximately:

- 20 minutes for an accreditation organization to provide a detailed description of the accreditation organization's conformance to ISO 17011 and experience evaluating the conformance of certification bodies to Guide 65;
- 20 minutes for an accreditation organization to provide a detailed description of the accreditation organization's accreditation requirements and how the requirements complement the Principles of Proper Conduct for ONC–ACBs;
- 5 minutes for an accreditation organization to provide a copy of the procedures that would be used to monitor ONC–ACBs;
- 10 minutes for an accreditation organization to provide detailed information, including education and experience, about the key personnel who review certification bodies for accreditation; and
- 5 minutes for an accreditation organization to provide a copy of the procedures for responding to, and investigating, complaints against ONC–ACBs.

We did not receive any comments on our estimates for the burden associated with § 170.503(b). We added the requirement that accreditation organizations specify how their accreditation requirements will ensure the surveillance approaches used by ONC–ACBs include the use of consistent, objective, valid, and reliable methods. We do not believe that this additional requirement will appreciably increase the burden for accreditation organizations requesting ONC–AA status and that any potential increase in the burden can be accounted for in the 20 minutes allotted for providing a detailed description of the accreditation organization's accreditation requirements and how the requirements complement the Principles of Proper Conduct for ONC–ACBs. Therefore, we have maintained the same burden estimates we provided in the Proposed Rule.

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Accreditation Organization	2	1	1	2

B. Collection of Information: Application for ONC–ACB Status Under the Permanent Certification Program

Section 170.520 requires an organization to submit specific information to the National Coordinator to be considered for ONC–ACB status under the permanent certification program. We estimated in the Proposed Rule that there would be no more than 6 applicants for ONC–ACB status under the permanent certification program. We also provided estimates for the amount of time we believe will be necessary to complete an application for ONC–ACB status, *i.e.,* meet the requirements of § 170.520. Specifically, we estimated that it will take approximately:

- 10 minutes to provide the general identifying information requested in the application;
- 30 minutes to assemble the information necessary to provide documentation of accreditation by an ONC–AA; and
- 20 minutes to review and agree to the "Principles of Proper Conduct for ONC–ACBs."

Our burden estimates were based on the assumption that potential applicants will be familiar with many of the application requirements and will, for example, already have a majority—if not all—of the documentation requested

already developed and available before applying for ONC–ACB status.

Comments. We received one comment expressing agreement that most potential applicants would likely have a majority of the necessary documentation available when applying for ONC–ACB status. The commenter contended, however, that we should add a minimum of an additional 200 hours of staff time in consideration of the effort that will be required by an organization to become accredited, which the commenter noted is a prerequisite for applying for ONC–ACB status.

Response. We believe that the commenter's concerns related to the effort to become accredited are best addressed in our discussion of accreditation costs for potential ONC–ACB applicants under the regulatory impact analysis section of this final rule. The burden described under this section is for PRA purposes and is confined to the actual collection and submission of information required to apply for ONC–ACB status as specified in § 170.520. We note, however, that in the Proposed Rule we did not specifically attribute an amount of time (*i.e.,* burden) to identifying the type of authorization sought by a potential applicant. Although identifying the type of authorization sought is a requirement of § 170.520, we believe any time utilized to provide this information can be accounted for within the 10 minutes we have allotted for providing the requested general identifying information. Accordingly, our estimate of the burden for an applicant to collect and submit the information necessary to apply for ONC–ACB status remains the same as specified in the Proposed Rule.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Burden hours per response	Total burden hours
Applicant	6	1	1	6

C. Collection of Information: ONC–ACB Collection and Reporting of Information Related to Complete EHR and/or EHR Module Certifications

Section 170.523(f) requires an ONC–ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified as well as certain minimum information about each certified Complete EHR and/or EHR Module.

We did not receive any comments on this collection of information. We have, however, as we did for the related temporary certification program provision, specified in this final rule two additional reporting elements that must be submitted by ONC–ACBs on a weekly basis (*i.e.,* clinical quality measures to which a Complete EHR or EHR Module has been certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary). ONC–ACBs will be capturing these additional reporting elements in conjunction with the other information we request that they report on a weekly basis. Consequently, we do not believe that the reporting of these two additional elements will increase the reporting burden for ONC–ACBs.

For the purposes of estimating the potential burden, we have maintained our prior assumptions. We assume that all of the estimated applicants will apply and become ONC–ACBs (*i.e.,* 6 applicants). We also assume that ONC–ACBs will report weekly (*i.e.,* respondents will respond 52 times per year). Finally, we assume that the information collections will be accomplished through electronic data collection and storage, which will be part of the normal course of business for ONC–ACBs. Therefore, with respect to this proposed collection of information, the estimated burden is limited to the actual electronic reporting of the information to ONC.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ONC–ACB Certification Results	6	52	1	312

D. Collection of Information: Records Retention Requirements

Section 170.523(g) requires ONC–ACBs to retain certification records for 5 years. In the Proposed Rule, we stated our belief, based on our consultations with NIST, that the 5-year requirement was in line with common industry practice and, consequently, would not represent an additional cost to ONC–ACBs. We did not receive any comments related to our assertion and, therefore, maintain our belief that the 5-year record retention requirement will not create a burden or additional cost for ONC–ACBs.

E. Collection of Information: Submission of Surveillance Plan and Surveillance Results

Section 170.523(i) requires an ONC–ACB to submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results.

For the purposes of estimating the potential burden, we assume that all of the estimated number of applicants for the permanent certification program (*i.e.,* six) will become ONC–ACBs. We anticipate that the burden for each ONC–ACB will be the same based on the following assumptions. We assume that all surveillance plans will be fairly comparable. We also assume that all ONC–ACBs will, on average, have a similar burden in submitting results. Finally, we assume that an ONC–ACB will submit a copy of their annual surveillance plan and annually report surveillance results by either electronic transmission or paper submission. In either instance, we believe that an ONC–ACB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. Therefore, we estimate that an ONC–ACB will annually allocate 1 hour to submit the

plan (response #1) and 1 hour to report the results (response #2). Our estimates are expressed in the table below.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ONC–ACB Surveillance Plan and Results	6	2	1	12

As required by section 3504(h) of the PRA, we have submitted a copy of this document to OMB for its review of these information collection requirements.

VI. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). Based on the analysis of costs and benefits that follows, we have determined that this final rule covering the permanent certification program is not an economically significant rule because we estimate that the overall costs and benefits associated with the permanent certification program, including the costs associated with the testing and certification of Complete EHRs and EHR Modules, to be less than $100 million per year. Nevertheless, because of the public interest in this final rule, we have prepared an RIA that to the best of our ability presents the costs and benefits of the final rule.

B. Why is this rule needed?

As stated in earlier sections of this final rule, section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. This final rule is needed to outline the processes by which the National Coordinator would exercise this authority to authorize certain organizations to certify Complete EHRs, EHR Modules, and/or other types of HIT. As to Complete EHRs and EHR Modules, once certified, they will be able to be used by eligible professionals and eligible hospitals as, or be combined to create, Certified EHR Technology. Eligible professionals and eligible hospitals who seek to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs are required by statute to use Certified EHR Technology.

C. Executive Order 12866—Regulatory Planning and Review Analysis

1. Comment and Response

Comments. As recited in the Temporary Certification Program final rule, we received a few comments that expressed concerns that the costs we attributed in the Proposed Rule related to the testing and certification of Complete EHRs and EHR Modules were too high, unrealistic, and unreliable. One commenter requested that we remove our cost estimates because they believed they were based on a monopolistic pricing structure. Other commenters indicated that we should regulate the pricing related to testing and certification in order to ensure that prices were not exorbitant and did not preclude smaller Complete EHR and EHR Module developers from being able to attain certification for their EHR technology.

Response. We understand the commenters' concerns; however, we have a responsibility to put forth a good faith effort to estimate the potential costs associated with this final rule. Part of that effort includes using the best available data to inform our assumptions and estimates. While we were open to revising our cost estimates in response to public comment, in no instance did a commenter provide alternative estimates or reference additional information from which we could base revisions. Conversely, we believe that commenters who expressed concerns about the potential costs, largely did so from the perspective of stating a request that we ensure the costs for testing and certification were not prohibitively high.

While we understand these commenters' perspectives, we do not believe that it is appropriate to dictate the minimum or maximum amount an ONC–ACB should be able to charge for certifying a Complete EHR or EHR Module. Based on the number of applicants we have granted ONC–ATCB status, we anticipate that we will there will be multiple ONC–ACBs that will compete for market share under the permanent certification program. As a result of this expected competition, we believe that there could also be increased downward pressure on the costs associated with testing and certification. If that cost pressure occurs, we believe that the upper ranges of the cost estimates we provide in this final rule could be overestimates.

Comments. We received one comment expressing agreement that most potential applicants would likely have a majority of the necessary documentation available when applying for ONC–ACB status. The commenter contended, however, that we should add a minimum of an additional 200 hours of staff time in consideration of the effort that will be required by an organization to become accredited.

Response. We believe that attributing 200 hours of staff time for preparing and participating in the accreditation process is reasonable. We also believe that it is appropriate to calculate the cost of the staff time at a position equivalent to a Federal GS–15, Step 1 employee. Accordingly, we have supplemented our original cost estimates to account for this staff time and have provided revised total cost estimates for accreditation and the ONC–ACB application process under the section titled "Application Process for ONC–ACB Status" in this RIA.

Comments. Some commenters questioned our estimates related to the number of EHR Modules we expected to be tested and certified. One commenter suggested that the number of self-developed EHR Modules should be much higher than we estimated. Other commenters expressed that this rule

needed to account for other costs associated with testing and certification (*e.g.,* reprogramming a Complete EHR or EHR Module) and not just the costs associated with the application process and for Complete EHRs and EHR Modules to be tested and certified. One commenter suggested that if our estimates of the number of EHR Modules and Complete EHRs that will be tested and certified and the costs for testing and certification are accurate, then the commenter contended that there will not be a sufficient market for sustaining ONC–ACBs and, therefore, ONC should assume all costs for testing and certification.

Response. As discussed in the Temporary Certification Program final rule (75 FR 36197), the certification programs final rules are part of a coordinated rulemaking effort. Each rule accounts for its specific effects. In the "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" interim final rule (75 FR 2038), we summarized these effects as follows:

> While there is no bright line that divides the effects of this interim final rule and the other two noted above, we believe that each analysis properly focuses on the direct effects of the provisions it creates. This interim final rule estimates the costs commercial vendors, open source developers, and relevant Federal agencies will incur to prepare Complete EHRs and EHR Modules to be tested and certified to adopted standards, implementation specifications, and certification criteria. The Medicare and Medicaid EHR Incentive Programs proposed rule estimates the impacts related to the actions taken by eligible professionals or eligible hospitals to become meaningful users, including purchasing or self-developing Complete EHRs or EHR Modules. The HIT Certification Programs proposed rule estimates the testing and certification costs for Complete EHRs and EHR Modules.

As result, we estimate in this final rule, as we had before, the effects of the application process for ONC–ACB status and the costs for Complete EHRs and EHR Modules to be tested and certified by ONC–ACBs. The HIT Standards and Certification Criteria final rule (75 FR 44590) provides our final analysis of the estimated costs commercial vendors, open source developers, and relevant Federal agencies will incur to prepare Complete EHRs and EHR Modules to be tested and certified to adopted standards, implementation specifications, and certification criteria, while the Medicare and Medicaid EHR Incentive Programs final rule (75 FR 44314) provides a final analysis of the impacts related to the actions taken by eligible professionals or eligible hospitals to become meaningful users, including purchasing or self-developing Complete EHRs or EHR Modules.

As we stated in the Temporary Certification Program final rule, with respect to EHR Modules, especially self-developed EHR Modules, we agree with those commenters regarding our estimates and have provided revised estimates that factor in a potential larger number of self-developed EHR Modules. While neither commenter who offered this concern related to EHR Modules provided any data to substantiate their claims, we determined that this revision was necessary because we had previously grouped self-developed Complete EHRs and EHR Modules together. Upon further review and other comments addressed above regarding EHR Modules, we believe that in order to provide a more accurate estimate, self-developed Complete EHRs and EHR Modules should be separately accounted for. We believe our prior estimates related to self-developed Complete EHRs and EHR Modules are more appropriately attributable to the number of self-developed Complete EHRs. Accordingly, we have developed new estimates (captured in the discussion and tables below) for the number of self-developed EHR Modules that we believe will be presented for testing and certification under the permanent certification program. We believe that our new estimates indicate that there will be a sufficient market to sustain an appropriate amount of ONC–ACBs necessary for the success of the permanent certification program. Further, we do not believe that it is appropriate for ONC to enter the market where private entities have concluded that there is a sufficient market for the testing and certification of HIT to be willing to perform the testing and certification of HIT. This conclusion has arguably been validated by the fact that 5 private entities have already become ONC–ATCBs under the temporary certification program.

2. Executive Order 12866 Final Analysis

As required by Executive Order 12866, we have examined the economic implications of this final rule as it relates to the permanent certification program. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a regulation as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, or in a material way adversely affecting the economy, a sector of the economy, competition, or jobs. While this final rule is therefore not "economically significant," as defined by Executive Order 12866, OMB has determined that this final rule constitutes a "significant regulatory action" as defined by Executive Order 12866 because it raises novel legal and policy issues.

a. Permanent Certification Program Estimated Costs

i. Request for ONC–AA Status

Costs for Accreditation Organizations

We believe that at most two accreditation organizations will prepare and submit the information sought by the National Coordinator. Additionally, we estimate that it will take 1 hour to prepare and submit a request for ONC–AA status. We believe that an employee equivalent to the Federal Salary Classification of GS–15 Step 1 would be responsible for preparing and submitting the required information. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, DC, as published by the OPM, to calculate our cost estimates. We have also calculated the costs of an employee's benefits while preparing and submitting the required information to be considered for ONC–AA status. We have calculated these costs by assuming that an accreditation organization expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our cost estimates are expressed in Table 2 below.

TABLE 2—PERMANENT CERTIFICATION PROGRAM: COST TO ACCREDITATION ORGANIZATIONS TO SUBMIT THE INFORMATION REQUIRED TO BECOME AN ONC–AA

Requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Total cost per applicant
Submission of Request for ONC–AA Status	GS–15 Step 1	1	$59.30	$21.35	$80.65

Using our estimates above, we believe that the cost to submit the information required to become an ONC–AA will be $81 and the total cost for the two accreditation organizations that we estimate will submit requests for ONC–AA status will be $161. Based on our estimate of two accreditation organizations submitting the required documentation to be considered for ONC–AA status and on the requirement that an ONC–AA be selected every three years, we estimate the annualized cost of requesting ONC–AA status to be $54.

Costs to the Federal Government

We anticipate that there will be costs associated with reviewing the information provided by accreditation organizations requesting to become an ONC–AA under the permanent certification program. We believe that a GS–15 Step 1 employee will review the submissions and the National Coordinator (or designated representative) will issue final decisions on all submissions. We anticipate that it will take 40 hours to review all submissions and reach a final decision on the best qualified accreditation organization. This estimate includes the time necessary to review the additional documentation that is now required to be submitted related to an accreditation organization's proposed administration of surveillance by ONC–ACBs and to prepare a briefing for the National Coordinator on approving the best qualified ONC–AA. This estimate also includes the time of the National Coordinator and other senior executive officials devoted to reaching a decision on the best qualified ONC–AA. Their time has been included in the 40 hour estimate at the GS–15 cost level. We estimate the Federal government's overall cost to review the submissions and approve an ONC–AA to be $3,226. Based on our estimate of two accreditation organizations submitting the required documentation to be considered for ONC–AA status and on the requirement that an ONC–AA be selected every three years, the annualized cost to the Federal government for reviewing the submissions for ONC–AA status will be $1,075. If we notify the public of the selection of the ONC–AA by posting the information on our Web site and/or by issuing a press release, we believe that we will incur negligible costs from these actions.

ii. Application Process for ONC–ACB Status

Costs for Applicant

Similar to the temporary certification program, an applicant for ONC–ACB status will be required to submit an application. However, unlike the temporary certification program, an applicant for ONC–ACB status must be accredited in order to be a qualified ONC–ACB applicant. As specified in the Proposed Rule, we estimate that there will be 6 applicants for ONC–ACB status under the permanent certification program and that those 6 applicants will first seek and become accredited by an ONC–AA. Because accreditation will include a demonstration of conformance to Guide 65 for all organizations that seek to be accredited, we do not believe that there will be a difference in the cost of accreditation for organizations who seek to become ONC–ACBs for EHR Modules versus ONC–ACBs for Complete EHRs.

Based on our consultations with NIST, we estimate that it will take approximately 2 to 5 days for an ONC–AA to complete the accreditation process. We anticipate that accreditation applicants with incur an estimated $5,000 administrative fee and the cost of the accreditation assessment will be approximately $15,000. In response to public comment, we have calculated a cost for the staff time necessary to prepare and participate in the accreditation assessment. We have accepted the commenter's suggestion that 200 hours of staff time is appropriate to attribute to preparation and participation in the accreditation assessment and have calculated the corresponding cost for this time based on the assumption that an employee equivalent to a Federal GS–15 employee would be responsible for preparation and participation in the accreditation assessment. A GS–15 employee's hourly wage with benefits is approximately $80.65. Therefore, the estimated staff cost for accreditation is $16,130.

We expect that the accreditation renewal process will occur once between 2012 and 2016 for each ONC–ACB and assume that the accreditation renewal process will be less onerous than the initial accreditation process because an ONC–ACB will be able to rely on the information it previously prepared for its initial accreditation as well as any such information it has produced during the ongoing maintenance of its accreditation. Additionally, because the estimated number of organizations that could become an ONC–AA is small, we believe that it is reasonable to assume that the ONC–ACB would be accredited by the same ONC–AA and thus a completely new review of the ONC–ACB may not be necessary. We believe a completely new review would likely not be necessary because the ONC–AA will already be familiar with the ONC–ACB and have its documentation on file, and we do not expect that an ONC–ACB will make such drastic changes to its policies or procedures which will necessitate a lengthy assessment of their competency by an ONC–AA.

We estimate that it will take no more than 3 days to conduct the accreditation renewal process and that the accreditation assessment will cost $10,000. In addition, we have similarly added a cost estimate to account for staff time to prepare and participate in the accreditation renewal process. As with our other renewal cost estimates, we anticipate that a reduced amount of staff time will be required. We have estimated that an employee equivalent to a GS–15 Federal employee will be responsible for preparation and participation in the accreditation renewal process and that no more than 100 hours of the employee's time will be required. As noted, a GS–15 employee's hourly wage with benefits is approximately $80.65. Therefore, the estimated staff cost for an accreditation renewal assessment is $8,065.

The total estimated cost for an ONC–ACB to become accredited is $36,130 and the total estimated cost for it to renew its accreditation is $18,065. These estimated costs are expressed in Table 4 below.

After becoming accredited by an ONC–AA, an applicant for ONC–ACB

status will incur minimal costs to prepare and submit an application to the National Coordinator. As noted in the collection of information section, we believe that it will take 10 minutes to provide the general information requested in the application, 30 minutes to assemble the information necessary to provide documentation of accreditation by an ONC–AA, and 20 minutes to review and agree to the "Principles of Proper Conduct for ONC–ACBs." We believe that these time estimates will also hold true when applying to renew ONC–ACB status.

Based on our consultations with NIST, we believe that an employee equivalent to the Federal Salary Classification of GS–9 Step 1 could provide the required general identifying information and documentation of accreditation status. We believe that an employee equivalent to the Federal Salary Classification of GS–15 Step 1 would be responsible for reviewing and agreeing to the "Principles of Proper Conduct for ONC–ACBs." We have taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, DC, as published by the OPM, to calculate our cost estimates. We have also calculated the costs of an employee's benefits while completing the application. We have calculated these costs by assuming that an applicant expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. We believe that these same assumptions hold true for applying to renew ONC–ACB status. Our cost estimates are expressed in Table 3 below.

TABLE 3—PERMANENT CERTIFICATION PROGRAM: COST TO APPLICANTS TO APPLY TO BECOME ONC–ACBS AND COST FOR ONC–ACBS TO APPLY FOR STATUS RENEWAL

Requirement	Employee equivalent	Burden hours	Employee hourly wage rate	Cost of employee benefits per hour	Cost per applicant
General Identifying Information	GS–9 Step 1	10/60	$22.39	$8.06	$5.07
Documentation of Accreditation	GS–9 Step 1	30/60	22.39	8.06	15.23
Principles of Proper Conduct	GS–15 Step 1	20/60	59.30	21.35	26.88
Total Cost per Applicant					$47.18

We have estimated the applicant costs and ONC–ACB renewal costs through 2016, but no further, because we believe that it is premature to assume how the meaningful use requirements will change when incentive payments are no longer available for eligible professionals and eligible hospitals under the Medicare EHR incentive program and what impact, if any, those potential changes will have on the permanent certification program. Using our estimates above, we believe that the average initial cost for an applicant to become accredited and apply to be an ONC–ACB will be approximately $36,177 and the total cost for all 6 applicants will be approximately $217,062. We estimate that between 2012 and 2016 that all applicants will renew their accreditation and ONC–ACB status once. As noted, we assume that the costs for an ONC–ACB to renew its status with the National Coordinator will be similar in burden to its initial application. We believe that the average cost for an ONC–ACB to renew its accreditation and ONC–ACB status will be approximately $18,112 and the total renewal costs for all ONC–ACBs will be approximately $108,672. We estimate that the total costs of the accreditation, application and renewal processes under the proposed permanent certification program between 2012 and 2016 would be approximately $54,289 per applicant/ONC–ACB and approximately $325,734 for all applicants/ONC–ACBs. Based on our cost estimate timeframe of 5 years (2012 through 2016), the annualized cost would be $65,147.

TABLE 4—PERMANENT CERTIFICATION PROGRAM: TOTAL COSTS OF CERTIFICATION ACCREDITATION, APPLYING FOR ONC CERTIFICATION AUTHORIZATION, AND ACCREDITATION AND AUTHORIZATION RENEWAL BETWEEN 2012 AND 2016

Anticipated number of applicants	Cost of accreditation per applicant	Cost to apply for certification authorization per applicant	Cost to renew accreditation per applicant	Cost to renew ONC–ACB status	Total cost estimate per applicant/ ONC–ACB
6	$36,130	$47	$18,065	$47	$54,289
Total Cost of Accreditation, Application and Renewal					$325,734

Costs to the Federal Government

We estimate the cost to develop the ONC–ACB application to be $350 based on the 5 hours of work we believe it will take a Federal Salary Classification GS–14 Step 1 employee located in Washington, DC to develop an application form. We also anticipate that there will be costs associated with reviewing applications under the permanent certification program. We expect that a GS–15 Step 1 employee will review the applications and the National Coordinator (or designated representative) will issue final decisions on all applications. We anticipate that it will take approximately 20 hours to review and reach a final decision on each application. This estimate assumes a satisfactory application (*i.e.,* no formal deficiency notifications) and includes the time necessary to verify the information in each application and prepare a briefing for the National Coordinator. We estimate the cost for the application review process to be $10,392. As a result, we estimate the Federal government's overall cost of administering the entire application process at approximately $10,742. Based on our cost estimate timeframe of 5 years (2012 through 2016), the

annualized cost to the Federal government will be $2,148.

As previously noted, we will also post the names of applicants granted ONC–ACB status on our Web site. We believe that there will be minimal cost associated with this action and have calculated the potential cost to be approximately $312 on an annual basis for posting and maintaining the information on our Web site (a maximum of 6 hours of work for a Federal Salary Classification GS–12 Step 1 employee located in Washington, DC).

iii. Testing and Certification of Complete EHRs and EHR Modules

Section 3001(c)(5)(A) of the PHSA indicates that certification is a voluntary act; however, due to the fact that the Medicare and Medicaid EHR Incentive Programs require eligible professionals and eligible hospitals to use Certified EHR Technology in order to qualify for incentive payments, we anticipate that Complete EHR and EHR Module developers will seek to have their HIT tested and certified under the permanent certification program.

As previously stated in our discussion of the appropriate timeframe for estimating costs for the ONC–ACB application process, we estimate costs through 2016, but no further, because we believe that it is premature to assume how the meaningful use requirements will change when incentive payments are no longer available for eligible professionals and eligible hospitals under the Medicare EHR incentive program. Although CMS intends to promulgate updates to the meaningful use stages every 2 years, we assume that there could be more time between stages (*i.e.,* greater than 2 years) in years when incentive payments are no longer available under the Medicare EHR incentive program based on evaluations of earlier meaningful use stages, public feedback, and other factors, which could affect when Complete EHRs and/or EHR Modules would need to be recertified. However, we do expect meaningful use requirements between 2012 and 2016 to become more demanding and iterate every 2 years. Therefore, we can assume that Complete EHRs and EHR Modules will need to be tested and certified twice during this time period.

As specified in the Temporary Certification Program final rule, we believe that approximately 93 commercial/open source Complete EHRs and 50 EHR Modules will be tested and certified to the 2011/2012 certification criteria adopted by the Secretary. In addition to the testing and certification of these Complete EHRs and EHR Modules, we anticipate that a percentage of eligible professionals and eligible hospitals will themselves incur the costs associated with the testing and certification of their self-developed Complete EHR or EHR Module(s) to the 2011/2012 certification criteria adopted by the Secretary.

With respect to the potential for eligible professionals to seek testing and certification for a self-developed Complete EHR, DesRoches found that only 5% of physicians are in large practices of over 50 doctors.[4] Of these large practices, 17% use an "advanced EHR system" that could potentially be tested and certified if it were self-developed (we assume that smaller physician practices do not have the resources to self-develop a Complete EHR). We are unaware of any reliable data on the number of large practices who may have a self-developed Complete EHR for which they would seek to be tested and certified. As a result, we have developed an estimate based on currently available data. We believe that the total number of eligible professionals in large practices who both possess an IT staff with the resources to develop and support a Complete EHR and would seek to have such a self-developed Complete EHR tested and certified will be low—no more than 10%. By taking CMS's estimate of approximately 550,000 eligible professionals (75 FR 44548) we multiply through by the numbers above ($550{,}000 \times .05 \times .17 \times .10$) and then divide by a practice size of at least 50 which yields approximately 9 self-developed Complete EHRs designed for an ambulatory setting that could be submitted for testing and certification to the 2011/2012 certification criteria adopted by the Secretary. Additionally, we believe that a reasonable estimate for the number of large practices with the IT staff and resources to self-develop an EHR Module and that would seek to have such an EHR Module tested and certified can also be derived from the calculation above but with a few differences. We start with the total number of large practices from the calculation above (~94). We then assume an average number (1.25) of self-developed EHR Modules for this group of large practices and further refine this estimate by providing low and high probability assumptions (10% and 70%, respectively) to represent the likelihood that any one of these large practices possesses a self-developed EHR Module that they would seek to have tested and certified. Our calculations produce a minimum estimate of 12 and a maximum estimate of 82 EHR Modules that may be presented for testing and certification to the 2011/2012 certification criteria adopted by the Secretary. Given that no commenter provided data to further support this estimate, we believe that our maximum number of self-developed EHR Modules estimate is generous. While we do not dispute that practice sizes smaller than 50 could also possess self-developed EHR Modules, we believe those smaller practices will be the exception, not the rule, and that separately calculating a total for these smaller practices would produce a negligible amount of EHR Modules to add to our overall range.

With respect to eligible hospitals, similar to eligible professionals, we believe that only large eligible hospitals would have the IT staff and resources available to possess a self-developed Complete EHR that they would seek to have tested and certified. Again, we are unaware of any reliable data on the number of eligible hospitals who may have a self-developed Complete EHR for which they would seek to be tested and certified. Further, we believe that with respect to EHR Modules the probability varies across different types of eligible hospitals regarding their IT staff resources and ability to self-develop an EHR Module and seek to have it tested and certified. As a result, we have developed estimates based on currently available data. We have based our calculations on the Medicare eligible hospital table CMS provided in its final rule (Table 25) (75 FR 44553) which conveys hospital IT capabilities according to three levels of adoption by hospital size according to the 2008 AHA annual survey. These three levels included: (1) Hospitals which had already implemented relatively advanced systems that included CPOE systems for medications; (2) hospitals which had implemented more basic systems through which lab results could be shared, but not CPOE for medications; and (3) hospitals starting from a base level either neither CPOE or lab reporting. CMS indicated that CPOE for medication standard was chosen because expert input indicated that the CPOE standard in the proposed meaningful use definition will be the hardest one for hospitals to meet.

As stated above, we believe that only large hospitals (defined in Table 25 as those with 400+ beds) would have the IT staff and resources to develop, support, and seek the testing and certification of a self-developed

[4] DesRoches, CM *et al.* Electronic Health Records in Ambulatory Care—A National Survey of Physicians, New England Journal of Medicine, July 2008; 359:50–60.

Complete EHR. CMS estimated that 379 large hospitals had met either "level 1" or "level 2." As a result, we estimate that approximately 10% of these large eligible hospitals have a self-developed Complete EHR and would seek to have it tested and certified. This equals about 38 self-developed Complete EHRs that we could expect to be tested and certified to the 2011/2012 certification criteria adopted by the Secretary. We believe that this estimate is generous and that a good portion of the eligible hospitals that would likely seek to qualify for incentive payments with self-developed Complete EHRs would only do so for meaningful use Stage 1. After meaningful use Stage 1 we anticipate that the number of eligible hospitals that would incur the costs of testing and certification themselves will go down because the effort involved to maintain a Complete EHR may be time and cost prohibitive as the Secretary continues to adopt additional certification criteria to support future stages of meaningful use.

With respect to hospital self-developed EHR Modules, we believe the probability varies across different types of eligible hospitals (CAHs, Small/Medium, and Large) regarding their IT staff resources and ability to self-develop EHR Modules. For each hospital type, we have estimated a minimum and a maximum number of EHR Modules that we could expect to be self-developed and presented for testing and certification to the 2011/2012 certification criteria adopted by the Secretary. For CAHs, we estimate a minimum of 7 and a maximum of 68 EHR Modules. For small and medium hospitals, we estimate a minimum of 163 and a maximum of 488. For large hospitals, we estimate a minimum of 190 and a maximum of 531. Again, we believe that our maximum estimates of self-developed EHR Modules are generous; however, to examine how we reached our estimates, please review our calculations specified in Table 5 below.

TABLE 5—ESTIMATED NUMBER OF SELF-DEVELOPED EHR MODULES DESIGNED FOR AN INPATIENT SETTING STRATIFIED BY TYPE OF ELIGIBLE HOSPITAL FOR TESTING AND CERTIFICATION TO THE 2011/2012 CERTIFICATION CRITERIA ADOPTED BY THE SECRETARY

Type of eligible hospital	Number of EHs	Percent with EHR Module (low)	Percent with EHR Module (high)	Average number of EHR Modules, if any	Miniml number of EHR Modules	Maximum number of EHR Modules
CAH	616	1	10	1.1	7	68
S/M	2169	5	15	1.5	163	488
Large	379	25	70	2.0	190	531
Total	3164				360	1087

Even though under the permanent certification program the costs for testing and certification could presumably be attributed to different entities (*i.e.,* testing costs to a NVLAP-accredited testing laboratory and certification costs to an ONC–ACB), we have included them together in an effort to reflect the overall effect of this final rule. In addition, our cost range for the testing and certification of Complete EHRs and EHR Modules includes consideration of how the testing and certification will be conducted (*i.e.,* by remote testing and certification, on-site testing and certification, or at the ONC–ATCB and for the complexity of an EHR Module).

As recited in the Proposed Rule, CCHIT testified on July 19, 2009 in front of the HIT Policy Committee on the topic of EHR certification, including the certification of EHR Modules. CCHIT estimated that "EHR-comprehensive" according to CCHIT certification criteria would have testing and certification costs that would range from approximately $30,000 to $50,000. CCHIT also estimated that the testing and certification of EHR Modules would range from approximately $5,000 to $35,000 depending on the scope of the testing and certification. We believe that these estimates provide a reasonable foundation and have used them for our cost estimates for the temporary certification program and as the basis for estimating costs for the permanent certification program. However, we assume that competition in the testing and certification markets will reduce the costs of testing and certification as estimated by CCHIT but we are unable to provide a reliable estimate at this time of what the potential reduction in costs might be.

In creating tables 6 through 13 below, we made the following assumptions:

- The cost for testing and certification will remain the same in the permanent certification program as they were in the temporary certification program even with the additional requirement of surveillance on the part of ONC–ACBs (which we would expect to be included in the cost they charge Complete EHR and/or EHR Module developers). We believe this is a reasonable assumption because of the low and high cost ranges we have estimated.
- That testing and certification costs will be unevenly distributed across subsequent years. We assume that there will be an increase in the year preceding the next stage of meaningful use and a decline between stages because Complete EHR and EHR Module developers will likely want to have their products certified as soon as possible to new standards and certification criteria so that they can be available to eligible professionals and hospitals for meaningful use purposes. With respect to the peak years for when testing and certification costs would most likely occur, we assume that those peak years will be 2012 and 2014, the years preceding the proposed start dates of meaningful use Stages 2 and 3, respectively. We assume that an increase would encompass 85% of the Complete EHRs and EHR Modules to be certified, which would represent most, if not all, Complete EHRs and EHR Modules previously certified to the 2011/2012 certification criteria adopted by the Secretary and that the remaining 15% of testing and certification costs for 2013 would likely represent new EHR Module entrants to the HIT marketplace and Complete EHR or EHR Module developers who were late to get certified.
- We assume that commercial/open source Complete EHR developers will continue to consolidate due to mergers and acquisitions and that this consolidation would occur at a rate of 5% between meaningful use stages. Therefore, we believe that fewer commercial/open source Complete EHRs will need to be tested and certified prior to each meaningful use stage.

• Conversely, we assume that the number of commercial/open source-developed EHR Modules that would need to be tested and certified to meet associated meaningful use Stage 2 (2013/2014) certification criteria and beyond will grow at a rate of 20% between meaningful use stages (*i.e.,* based on our prior estimate of 50 EHR Modules between 2010 and 2012, there would be 10 new modules developed during 2012 and during meaningful use Stage 2 to meet certification criteria associated with meaningful use Stage 2). We believe our growth rate is reasonable because the cost barrier for EHR Modules to enter the market will be much less than a Complete EHR. Coupled with the ability of small or start-up HIT developers to enter the market we believe that the potential of EHR Modules will lead to a constant stream of new entrants year after year.

• The number of eligible professionals and eligible hospitals that incur the testing and certification costs for their self-developed Complete EHRs for meaningful use Stage 2 will drop by 50% in 2012 and another 25% in 2014 and level out after 2014 due to our assumption, that by 2014, and the proposed start of meaningful use Stage 3, all of the eligible professionals and eligible hospitals who still have a self-developed Complete EHR are likely to maintain their HIT rather than switch to a commercial product.

• The number of eligible professionals and eligible hospitals that incur the testing and certification costs for their self-developed EHR Modules will remain in the range we have provided for testing and certification to the 2011/2012 certification criteria adopted by the Secretary. We believe this is the most reliable estimate at this time for a couple of reasons. First, we have provided a generous maximum estimate of EHR Modules that we believe will be self developed and should account for any potential increase in self-developed EHR Modules during future meaningful use stages. Second, and most importantly, we have no information that would suggest a particular direction for the market. We see the potential for a variety of ways that the market could progress, some of which include multiple self-developed EHR Modules being replaced by one commercial/open source EHR Module, more self-developed EHR Modules being created, or an equilibrium being created by eligible professionals and eligible hospitals switching from commercial to self-developed EHR Modules and vice versa. Without knowing the direction of the market, we believe that our estimated range of EHR Modules for testing and certification to the 2011/2012 certification criteria adopted by the Secretary is the most appropriate and reliable estimate to use for establishing projected testing and certification costs for meaningful use Stages 2 and 3.

• We assume that gap certification, as described in this final rule, will likely reduce the costs of certification. However, because of unknown variables such as the number of Complete EHRs and EHR Modules that will be eligible for gap certification and how readily ONC–ACBs will use gap certification, our cost estimates may vary from the actual costs for testing and certification to certification criteria associated with later stages of meaningful use.

As previously mentioned, we anticipate that the temporary certification program will sunset on December 31, 2011, or on a subsequent date that is determined to be appropriate by the National Coordinator. Therefore, it is quite possible that the permanent certification program could commence at the start of 2012 and ONC–ACBs would begin conducting certifications at that time. Taking this into consideration, as similarly calculated for the temporary certification program costs (75 FR 36201), we have estimated and attributed to the permanent certification program's costs the 2012 costs for testing and certifying 15% of the overall number of Complete EHRs and EHR Modules that could potentially be tested and certified to the 2011/2012 certification criteria adopted by the Secretary. This 15% 2012 cost for testing and certification is represented by 15% of the number of each type of Complete EHR and EHR Module we have estimated would be tested and certified to the 2011/2012 certification criteria adopted by the Secretary multiplied by the appropriate estimated costs for testing and certification. The overall cost is expressed in Table 6 below. It should be noted that the cost estimates are different than the cost estimates expressed in the Temporary Certification Program final rule for 2012 because they are based on an increased number of large practice groups and eligible hospitals that may self-develop a Complete EHR and/or EHR Module as specified in the Medicare and Medicaid EHR Incentive Programs final rule (75 FR 44548, 44553).

TABLE 6—DISTRIBUTED TOTAL COSTS FOR THE TESTING AND CERTIFICATION OF COMPLETE EHRS AND EHR MODULES TO THE 2011/2012 CERTIFICATION CRITERIA ADOPTED BY THE SECRETARY UNDER THE PERMANENT CERTIFICATION PROGRAM

Year	Ratio	Total low cost estimate ($M)	Total high cost estimate ($M)	Total average cost estimate ($M)
2012	15%	$.95	$7.46	$3.30

The following tables represent estimated permanent certification program costs for the testing and certification of Complete EHRs and EHR Modules to meaningful use (MU) Stages 2 and 3 and include:

• MU Stage 2: Commercial/Open Source Complete EHRs and EHR Modules—Table 7;

• MU Stage 2: Self-developed Complete EHRs—Table 8;

• MU Stage 2: Self-developed EHR Modules—Table 9;

• MU Stage 3: Commercial/Open Source Complete EHRs and EHR Modules—Table 10;

• MU Stage 3: Self-developed Complete EHRs—Table 11;

• MU Stage 3: Self-developed EHR Modules—Table 12.

Table 7 illustrates the costs for testing and certification of commercial/open source Complete EHRs and EHR Modules to meaningful use Stage 2. We have factored in the assumed 5% reduction in the estimated number of Complete EHRs presented for meaningful use Stage 1 and 20% increase of the estimated number of EHR Modules presented for meaningful use Stage 1. That is, we believe there will be approximately 88 commercial/open source Complete EHRs and 60 EHR Modules that will be tested and certified to meaningful use Stage 2.

TABLE 7—MU STAGE 2: COSTS FOR TESTING AND CERTIFICATION OF COMMERCIAL/OPEN SOURCE COMPLETE EHR AND EHR MODULE UNDER THE PERMANENT CERTIFICATION PROGRAM

Type	Number tested and certified	Cost per complete EHR/EHR Module ($M)			Total cost for all complete EHRs/EHR Modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Commercial/Open Source Complete EHR	88	$0.03	$0.05	$0.04	$2.64	$4.40	$3.52
Commercial/Open Source EHR Module	60	0.005	0.035	0.02	0.30	2.10	1.20
Total	148				2.94	6.55	4.72

Table 8 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed Complete EHRs to meaningful use Stage 2. We have factored in the assumed 50% reduction of the estimated number of Complete EHRs presented for meaningful use Stage 1. That is, we believe there will be approximately 5 self-developed Complete EHRs for an ambulatory setting and 19 self-developed Complete EHRs for an inpatient setting that will be tested and certified to meaningful use Stage 2.

TABLE 8—MU STAGE 2: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED COMPLETE EHRS UNDER THE PERMANENT CERTIFICATION PROGRAM

Type	Number tested and certified	Cost per complete EHR ($M)			Total cost for all complete EHRs over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Self Developed Complete EHRs Ambulatory Setting	5	$0.03	$0.05	$0.04	$0.15	$0.25	$0.20
Self-Developed Complete EHRs Inpatient Setting	19	0.03	0.05	0.04	0.57	0.95	0.76
Total	23				0.72	1.20	0.96

Table 9 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed EHR Modules to meaningful use Stage 2. Based on our assumption, the estimated range of EHR Modules that will be presented for testing and certification to meaningful use Stage 2 will remain the same as for meaningful use Stage 1. That is, we believe there will be between 12 and 82 self-developed EHR Modules for an ambulatory setting attributable to large eligible professional practice groups that will be tested and certified to meaningful use Stage 2. In addition, we believe there will be between 360 and 1087 self-developed Complete EHRs for an inpatient setting attributable to CAHs, small/medium hospitals, and large hospitals that will be tested and certified to meaningful use Stage 2. In total, we believe there will be a minimum of 372 and a maximum of 1,169 self-developed EHR Modules that will be tested and certified to meaningful use Stage 2.

TABLE 9—MU STAGE 2: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED EHR MODULES UNDER THE PERMANENT CERTIFICATION PROGRAM

Self-Developed EHR Modules	Number tested and certified	Cost per EHR Module ($M)			Total cost for all EHR Modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Min number of EHR Modules	372	$0.005	$0.035	$0.02	$1.86	$13.02	$7.44
Max number of EHR Modules	1,169	0.005	0.035	0.02	5.85	40.92	23.38

Table 10 illustrates the costs for testing and certification of commercial/open source Complete EHRs and EHR Modules to meaningful use Stage 3. We have factored in the assumed 5% reduction in the estimated number of Complete EHRs presented for meaningful use Stage 2 and 20% increase in the estimated number of EHR Modules presented for meaningful use Stage 2. That is, we believe there will be approximately 84 commercial/open source Complete EHRs and 72 EHR Modules that will be tested and certified to meaningful use Stage 3.

TABLE 10—MU STAGE 3: COSTS FOR TESTING AND CERTIFICATION OF COMMERCIAL/OPEN SOURCE COMPLETE EHRS AND EHR MODULES UNDER THE PERMANENT CERTIFICATION PROGRAM

Type	Number tested and certified	Cost per complete EHR/EHR Module ($M)			Total cost for all complete EHRs/EHR Modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Commercial/Open Source Complete EHR	84	$0.03	$0.05	$0.04	$2.52	$4.20	$3.36
Commercial/Open Source EHR Module	72	0.005	0.035	0.02	0.36	2.52	1.44
Total	156				2.88	6.72	4.80

Table 11 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed Complete EHRs to meaningful use Stage 3. We have factored in the assumed 25% reduction in the estimated number of Complete EHRs presented for meaningful use Stage 2. That is, we believe there will be approximately 4 self-developed Complete EHRs for an ambulatory setting and 14 self-developed Complete EHRs for an inpatient setting that will be tested and certified to meaningful use Stage 3.

TABLE 11—MU STAGE 3: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED COMPLETE EHRS UNDER THE PERMANENT CERTIFICATION PROGRAM

Type	Number tested and certified	Cost per complete EHR ($M)			Total cost for all complete EHRs over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Self Developed Complete EHRs Ambulatory Setting	4	$0.03	$0.05	$0.04	$0.12	$0.20	$0.16
Self-Developed Complete EHRs Inpatient Setting	14	0.03	0.05	0.04	0.42	.70	.56
Total	18				0.54	.90	0.72

Table 12 illustrates the costs for testing and certification of eligible professional and eligible hospital self-developed EHR Modules to meaningful use Stage 3. Based on our assumption, the estimated range of EHR Modules that will be presented for testing and certification to meaningful use Stage 3 will remain the same as it did for meaningful use Stages 1 and 2. That is, we believe there will be between 12 and 82 self-developed EHR Modules for an ambulatory setting attributable to large eligible professional practice groups that will be tested and certified to meaningful use Stage 3. In addition, we believe there will be between 360 and 1087 self-developed Complete EHRs for an inpatient setting attributable to CAHs, small/medium hospitals, and large hospitals that will be tested and certified to meaningful use Stage 3. In total, we believe there will be a minimum of 372 and a maximum of 1,169 minimum self-developed EHR Modules that will be tested and certified to meaningful use Stage 3.

TABLE 12—MU STAGE 3: COSTS FOR TESTING AND CERTIFICATION OF SELF-DEVELOPED EHR MODULES UNDER THE PERMANENT CERTIFICATION PROGRAM

Self-developed EHR Modules	Number tested and certified	Cost per complete EHR Module ($M)			Total cost for all EHR Modules over 3-year period ($M)		
		Low	High	Mid-point	Low	High	Mid-point
Min number of EHR Modules	372	$0.005	$0.035	$0.02	$1.86	$13.02	$7.44
Max number of EHR Modules	1,169	0.005	0.035	0.02	5.85	40.92	23.38

Table 13 illustrates the 85% and 15% testing and certification cost distributions we estimate would be attributable to meaningful use Stages 2 and 3 (*i.e.,* between 2012 and 2016) under the permanent certification program. Additionally, we assume that 100% of self-developed Complete EHRs and EHR Modules would be certified in year that precedes the next meaningful use stage (*i.e.,* 2012 and 2014) because eligible professionals and eligible hospitals who remain self-developers will be motivated to ensure that their HIT can meet the definition of Certified EHR Technology prior to the beginning of a new meaningful use stage in order to avoid missing out on the incentives or being subject to downward payment adjustments. As a result, the costs for self-developers to get their Complete EHRs or EHR Modules are only attributed in Table 13 to the years 2012 and 2014. The totals multiplied by their respective percentages are derived from the tables above.

TABLE 13—ESTIMATED DISTRIBUTED YEARLY COSTS FOR THE TESTING AND CERTIFICATION OF COMPLETE EHRS AND EHR MODULES ASSOCIATED WITH MEANINGFUL USE STAGES 2 AND 3 UNDER THE PERMANENT CERTIFICATION PROGRAM

Meaningful Use State and Year(s)	Percentage	Type	Low ($M)	High ($M)	Mid-point ($M)
Stage 2:					
2012	85	Commercial/	$2.50	$5.57	$4.01
	100	Open Source SElf-Developed	2.58	42.12	16.37
2013/2014	15	Commercial/	0.44	0.98	.71
	0	Open Source Self-Developed	0	0	0
Stage 3:					
2014	85	Commercial/	2.45	5.71	4.08
	100	Open Source Self-Developed	2.40	41.82	16.13
2015/2016	15	Commercial/	0.43	1.01	0.72
	0	OpenSource Self-Developed	0	0	0

iv. Costs for Collecting, Storing, and Reporting Certification Results

Costs to ONC–ACBs

Under the permanent certification program, ONC–ACBs will be required to provide ONC, no less frequently than weekly, an up-to-date list of Complete EHRs and/or EHR Modules that have been tested and certified as well as certain minimum information about each certified Complete EHR and/or EHR Module.

As stated in the collection of information section, we will require the reporting of this information on a weekly basis and that it will take ONC–ACBs about an hour to prepare and electronically transmit the information to ONC each week (*i.e.,* respondents will respond 52 times per year). As also noted in the collection of information section and consistent with the Temporary Certification Program final rule, we have specified in this final rule two additional reporting elements that must be submitted by ONC–ACBs on a weekly basis (*i.e.,* clinical quality measures to which a Complete EHR or EHR Module has been tested and certified and, where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary). ONC–ACBs will be capturing these additional reporting elements in conjunction with the other information we request that they report on a weekly basis. Consequently, we do not believe that the reporting of these two additional elements will increase the reporting burden or costs for ONC–ACBs.

We believe that an employee equivalent to the Federal Classification of GS–9 Step 1 could complete the transmissions of the requested information to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, DC, as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the transmissions of the requested information. We have calculated these costs by assuming that an ONC–ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our cost estimates are expressed in Table 14 below.

TABLE 14—ANNUAL COSTS FOR AN ONC–ACB TO REPORT CERTIFICATIONS TO ONC

Program requirement	Employee equivalent	Annual burden hours per ONC–ACB	Employee hourly wage rate	Employee benefits hourly cost	Total cost per ONC–ACB
ONC–ACB Certification Results	GS–9 Step 1	52	$22.39	$8.06	$1,583.40

To estimate the highest possible cost, we assume that all of the estimated applicants (*i.e.,* six) that we anticipate will apply under the permanent certification program will become ONC–ACBs. Therefore, we estimate the total annual reporting cost under the permanent certification program to be $9,500.40.

Costs to the Federal Government

As stated previously in this final rule, we will post a comprehensive list of all certified Complete EHRs and EHR Modules on our Web site. We believe that there will be minimal cost associated with this action and have calculated the potential cost, including weekly updates, to be $10,784 on an annualized basis. This amount is based on 208 hours of yearly work of a Federal Salary Classification GS–12 Step 1 employee located in Washington, DC

v. Costs for Retaining Certification Records

We stated in the Proposed Rule that we believe that the requirement for ONC–ACBs to retain certification records for five years, as specified in § 170.523(g), is in line with common industry practices and, consequently, does not represent additional costs to ONC–ACBs. This determination was based on our consultations with NIST. We did not receive any public comments contrary to our determination and continue to adhere to our determination.

vi. Submission of Surveillance Plan and Surveillance Results

Costs to ONC–ACBs

Under the permanent certification program, ONC–ACBs will be required to submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator their surveillance results.

As stated in the collection of information section, we anticipate that the burden for each ONC–ACB will be the same based on the following assumptions. We assume that all surveillance plans will be fairly comparable. We also assume that all ONC–ACBs will, on average, have a similar burden in submitting results. Finally, we assume that an ONC–ACB will submit a copy of their annual surveillance plan and surveillance results by either electronic transmission or paper submission. In either instance, we believe that an ONC–ACB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. Therefore, we estimate that an ONC–ACB will annually allocate 1 hour to submit the surveillance plan and 1 hour to submit the surveillance results.

We believe that an employee equivalent to the Federal Classification of GS–9 Step 1 could complete the transmissions of the surveillance plan and surveillance results to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, DC as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the transmissions of the surveillance plan and surveillance results. We have calculated these costs by assuming that an ONC–ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Our cost estimates are expressed in Table 15 below.

TABLE 15—ANNUAL COSTS FOR AN ONC–ACB TO SUBMIT A SURVEILLANCE PLAN AND SURVEILLANCE RESULTS

Program requirement	Employee equivalent	Annual burden hours per ONC–ACB	Employee hourly wage rate	Employee benefits hourly cost	Total cost per ONC–ACB
ONC–ACB Surveillance Plan and Surveillance Results.	GS–9 Step 1	2	$22.39	$8.06	$60.90

To estimate the highest possible cost, we assume that all of the estimated applicants (*i.e.,* six) that we anticipate will apply under the permanent certification program will become ONC–ACBs. Therefore, we estimate the total annual costs for submitting surveillance plans and surveillance results will be $365.40.

Costs to the Federal Government

We believe that we will incur negligible costs in receiving ONC–ACBs' transmissions of surveillance plans and surveillance results.

vii. Overall Average Annual Costs by Entity

The following table provides a summary of our overall estimated annual costs for the entities that we project will incur costs under the permanent certification program (as specified in the RIA of this final rule). For ONC–AA applicants, we have averaged the application costs over a 3-year period because the duration of an ONC–AA's term is 3 years. For ONC–ACB applicants, we have averaged the application costs over a 5-year period to coincide with the timeframe used to estimate testing and certification costs for this final rule. In estimating the overall annual costs for an ONC–ACB, we averaged the estimated costs of ONC–ACB status renewal over a 3-year period because the duration of an ONC–ACB's term is 3 years. For commercial, open source and self-developers, we have provided the average of the mid-point estimated costs for the testing and certification of Complete EHRs and EHR Modules to certification criteria associated with meaningful use stages 2 and 3 over a 5-year period (*see also* Table 13). Estimated annual costs for the Federal government are averaged over the appropriate timeframe. For example, costs for reviewing and approving an ONC–AA are averaged over a 3-year period, while costs for reviewing ONC–ACB applications are averaged over a 5-year period. Table 16 is expressed in thousands of dollars ($1,000). To illustrate, $27 is expressed as .027 and $6.5 million is expressed as $6,500.00.

TABLE 16—OVERALL AVERAGE ANNUAL COSTS FOR ENTITIES UNDER THE PERMANENT CERTIFICATION PROGRAM

ONC–AA applicant	ONC–AA	ONC–ACB applicant	ONC–ACB	Commercial/open source developers	Self-developers	Federal Government
.027	N/A	7.24	7.68	1,900.00	6,500.00	14.32

* Costs are expressed in thousands of dollars ($1,000).

b. Permanent Certification Program Benefits

We believe that several benefits will accrue from the establishment of the permanent certification program. The permanent certification program will provide a stable, consistent and reliable program for the certification of Complete EHRs, EHR Modules and potentially other types of HIT. The permanent certification program will allow eligible professionals and eligible hospitals to adopt and implement Certified EHR Technology for future

meaningful use stages, such as Stages 2 and 3, and thus potentially qualify for incentive payments under the CMS Medicare and Medicaid EHR Incentive Programs. We further believe that the permanent certification program will meet our overall goals of accelerating health IT adoption and increasing levels of interoperability. At this time, we cannot predict how fast all of these savings will occur or their precise magnitude as they are partly dependent on future final rules for meaningful use and the subsequent standards and certification criteria adopted by the Secretary.

D. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For more information on the Small Business Administration's (SBA's) size standards, *see* the SBA's Web site.[5] For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. When conducting a RFA we are required to assess the potential effects of our rule on small entities and to make every effort to minimize the regulatory burden that might be imposed on small entities. We believe that the entities that are likely to be directly affected by this final rule are applicants for ONC–ACB status. Furthermore, we believe that these entities would either be classified under the North American Industry Classification System (NAICS) codes 541380 (Testing Laboratories) or 541990 (Professional, Scientific and Technical Services).[6] We believe that there will be up to 6 applicants for ONC–ACB status. According to the NAICS codes identified above, this would mean SBA size standards of $12 million and $7 million in annual receipts, respectively.[7] Because this segment of the HIT industry is in a nascent stage and is comprised of very few entities, we have been unable to find reliable data from which to determine what realistic annual receipts would be. However, based on our total estimates for Complete EHRs and EHR Modules to be tested and certified, we assume that the annual receipts of any one ONC–ACB could be in the low millions of dollars. Moreover, it is unclear, whether these entities may be involved in other testing and certification programs which would increase their annual receipts and potentially place them outside the SBA's size standards.

We believe that we have established the minimum amount of requirements necessary to accomplish our policy goals and that no appropriate regulatory alternatives could be developed to lessen the compliance burden for applicants for ONC–ACB status as well as ONC–ACBs once they have been granted such status by the National Coordinator. Moreover, we believe that this final rule will create direct positive effects for entities because their attainment of ONC–ACB status will permit them to test and certify Complete EHRs, EHR Modules, and/or possibly other types of HIT. Thus, we expect that their annual receipts will increase as a result of becoming an ONC–ACB.

We did not receive any comments related to our RFA analysis on the permanent certification program. As a result, we examined the economic implications of this final rule and have concluded that it will not have a significant impact on a substantial number of small entities. The Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

E. Executive Order 13132—Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications.

Nothing in this final rule imposes substantial direct requirement costs on State and local governments, preempts State law or otherwise has federalism implications. We are not aware of any State laws or regulations that conflict with or are impeded by our permanent certification program, and we did not receive any comments to the contrary in response to the Proposed Rule.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires cost-benefit and other analyses before any rulemaking if the rule includes a "Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is approximately $135 million. We did not receive any comments related to the permanent certification program on our analysis presented in the Proposed Rule. Therefore, we have determined that this final rule will not constitute a significant rule under the Unfunded Mandates Reform Act, because it imposes no mandates.

OMB reviewed this final rule.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

■ For the reasons set forth in the preamble, 45 CFR subtitle A, subchapter D, part 170, is amended as follows:

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 1. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 2. Add a new subpart E to part 170 to read as follows:

Subpart E—Permanent Certification Program for HIT

Sec.

[5] *http://sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.*

[6] *See* 13 CFR 121.201.

[7] The SBA references that annual receipts means "total income" (or in the case of a sole proprietorship, "gross income") plus "cost of goods sold" as these terms are defined and reported on Internal Revenue Service tax return forms. *http://www.sba.gov/idc/groups/public/documents/sba_homepage/guide_to_size_standards.pdf.*

Subpart E—Permanent Certification Program for HIT

§ 170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the permanent certification program for health information technology (HIT) administered by the National Coordinator for Health Information Technology.

§ 170.501 Applicability.

This subpart establishes the processes that applicants for ONC–ACB status must follow to be granted ONC–ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC–ACB status; the requirements that ONC–ACBs must follow to maintain ONC–ACB status; and the requirements of ONC–ACBs for certifying Complete EHRs, EHR Module(s), and other types of HIT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also establishes the processes accreditation organizations must follow to request approval from the National Coordinator and that the National Coordinator in turn will follow to approve an accreditation organization under the permanent certification program as well as certain ongoing responsibilities for an ONC–AA.

§ 170.502 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC–ACB by submitting an application for ONC–ACB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT resides or is being or has been implemented.

Development site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT was developed.

Gap certification means the certification of a previously certified Complete EHR or EHR Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).

ONC–Approved Accreditor or ONC–AA means an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

ONC–Authorized Certification Body or ONC–ACB means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the certification of Complete EHRs, EHR Module(s), and/or other types of HIT under the permanent certification program.

Providing or provide an updated certification means the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module(s).

Remote certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC–ACB to be physically present at the development or deployment site to conduct certification.

§ 170.503 Requests for ONC–AA status and ONC–AA ongoing responsibilities.

(a) The National Coordinator may approve only one ONC–AA at a time.

(b) *Submission.* The National Coordinator will publish a notice in the **Federal Register** to announce the 30-day period during which requests for ONC–AA status may be submitted. In order to be considered for ONC–AA status, an accreditation organization must submit a timely request in writing to the National Coordinator along with the following information to demonstrate its ability to serve as an ONC–AA:

(1) A detailed description of the accreditation organization's conformance to ISO/IEC17011:2004 (incorporated by reference in § 170.599) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);

(2) A detailed description of the accreditation organization's accreditation, requirements as well as how those requirements would complement the Principles of Proper Conduct for ONC–ACBs and ensure the surveillance approaches used by ONC–ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Detailed information on the accreditation organization's procedures that would be used to monitor ONC–ACBs;

(4) Detailed information, including education and experience, about the key personnel who review organizations for accreditation; and

(5) Procedures for responding to, and investigating, complaints against ONC–ACBs.

(c) *Preliminary selection.*

(1) The National Coordinator is permitted up to 60 days from the end of the submission period to review all timely submissions that were received and determine which accreditation organization is best qualified to serve as the ONC–AA.

(2) The National Coordinator's determination will be based on the information provided, the completeness of an accreditation organization's description of the elements listed in paragraph (b) of this section, and each accreditation organization's overall accreditation experience.

(3) The accreditation organization that is determined to be the best qualified will be notified that it has been selected as the ONC–AA on a preliminary basis, subject to the resolution of the reconsideration process in § 170.504. All other accreditation organizations will be notified that their requests for ONC–AA status have been denied. The accreditation organization that is selected on a preliminary basis shall not represent itself as the ONC–AA or perform accreditation(s) under the permanent certification program unless and until it receives written notice from the National Coordinator that it has been approved as the ONC–AA on a final basis pursuant to paragraph (d) of this section.

(4) Any accreditation organization that submits a timely request for ONC–AA status and is denied may request reconsideration in accordance with § 170.504.

(d) *Final approval.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in § 170.504(b), then that organization will be approved as the ONC–AA on a final basis. The accreditation organization that was selected as the ONC–AA on a preliminary basis pursuant to paragraph (c) of this section will be notified of this final decision and cannot request reconsideration or further review.

(2) If the National Coordinator determines that no accreditation organization has met the standard specified in § 170.504(b), then the organization that was selected as the ONC–AA on a preliminary basis pursuant to paragraph (c) of this section will be approved as the ONC–AA on a final basis.

(e) *ONC–AA ongoing responsibilities.* An ONC–AA must:

(1) Maintain conformance with ISO/IEC 17011:2004 (incorporated by reference in § 170.599);

(2) In accrediting certification bodies, verify conformance to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599) and ensure the surveillance approaches used by ONC–ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Verify that ONC–ACBs are performing surveillance in accordance with their respective annual plans; and

(4) Review ONC–ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC–ACBs with the conditions of their respective accreditations.

(f) *ONC–AA status.*

(1) An accreditation organization has not been granted ONC–AA status unless and until it is notified by the National Coordinator that it has been approved as the ONC–AA on a final basis pursuant to paragraph (d) of this section.

(2) An ONC–AA's status will expire not later than 3 years from the date its status was granted by the National Coordinator.

(3) The National Coordinator will accept requests for ONC–AA status, in accordance with paragraph (b) of this section, at least 180 days before the current ONC–AA's status is set to expire.

§ 170.504 Reconsideration process for requests for ONC–AA status.

(a) An accreditation organization that submits a timely request for ONC–AA status in accordance with § 170.503 and is denied may request reconsideration of the decision to deny its request for ONC–AA status.

(b) *Submission requirement.* To request reconsideration, an accreditation organization is required to submit to the National Coordinator, within 15 days of receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC–AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC–AA status and that the accreditation organization would have been selected as the ONC–AA pursuant to § 170.503(c) if those errors had been corrected. If the National Coordinator does not receive an accreditation organization's submission within the specified timeframe, then its request for reconsideration may be denied.

(c) *Review of submissions.* The National Coordinator is permitted up to 30 days to review all timely submissions that were received and determine whether an accreditation organization has met the standard specified in paragraph (b) of this section.

(d) *Decision.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC–AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied.

(2) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.505 Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an accreditation organization requesting ONC–AA status, the ONC–AA, an applicant for ONC–ACB status, or an ONC–ACB is the date on which the e-mail was sent.

(b) In circumstances where it is necessary for an accreditation organization requesting ONC–AA status, the ONC–AA, an applicant for ONC–ACB status, or an ONC–ACB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

§ 170.510 Types of certification.

Applicants may seek authorization from the National Coordinator to perform the following types of certification:

(a) Complete EHR certification; and/or

(b) EHR Module certification; and/or

(c) Certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

§ 170.520 Application.

Applicants must include the following information in an application for ONC–ACB status and submit it to the National Coordinator for the application to be considered complete.

(a) The type of authorization sought pursuant to § 170.510. For authorization to perform EHR Module certification, applicants must indicate the specific type(s) of EHR Module(s) they seek authorization to certify. If qualified, applicants will only be granted authorization to certify the type(s) of EHR Module(s) for which they seek authorization.

(b) General identifying, information including:

(1) Name, address, city, state, zip code, and Web site of applicant; and

(2) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.

(c) Documentation that confirms that the applicant has been accredited by the ONC–AA.

(d) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC–ACBs.

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

(a) Maintain its accreditation;

(b) Attend all mandatory ONC training and program update sessions;

(c) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify HIT;

(d) Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management including key certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to certify HIT.

(e) Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed to demonstrate compliance with the requirements of the permanent certification program;

(f) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified, which includes, at a minimum:

(1) The Complete EHR or EHR Module developer name (if applicable);

(2) The date certified;
(3) The product version;
(4) The unique certification number or other specific product identification;
(5) The clinical quality measures to which a Complete EHR or EHR Module has been certified;
(6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and
(7) Where applicable, the certification criterion or criteria to which each EHR Module has been certified.

(g) Retain all records related to the certification of Complete EHRs and/or EHR Module(s) for a minimum of 5 years;

(h) Only certify HIT, including Complete EHRs and/or EHR Module(s), that has been tested, using test tools and test procedures approved by the National Coordinator, by a/an:
(1) NVLAP-accredited testing laboratory; or
(2) ONC–ATCB when:
(i) Certifying previously certified EHR Module(s) if the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and no new certification criteria are applicable to the EHR Module(s); or
(ii) Performing gap certification.

(i) Submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results; and

(j) Promptly refund any and all fees received for:
(1) Requests for certification that are withdrawn while its operations are suspended by the National Coordinator;
(2) Certifications that will not be completed as a result of its conduct; and
(3) Previous certifications that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Module(s);

(k) Ensure adherence to the following requirements when issuing a certification to a Complete EHR and/or EHR Module(s):
(1) A Complete EHR or EHR Module developer must conspicuously include the following on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:
(i) "This [Complete EHR or EHR Module] is 20[XX]/20[XX] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments."; and
(ii) The information an ONC–ACB is required to report to the National Coordinator under paragraph (f) of this section for the specific Complete EHR or EHR Module at issue;
(2) A certification issued to a pre-coordinated, integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section, except that the certification must also indicate each EHR Module that is included in the bundle; and
(3) A certification issued to a Complete EHR or EHR Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

§ 170.525 Application submission.

(a) An applicant for ONC–ACB status must submit its application either electronically via e-mail (or web submission if available), or by regular or express mail.

(b) An application for ONC–ACB status may be submitted to the National Coordinator at any time.

§ 170.530 Review of application.

(a) *Method of review and review timeframe.*
(1) Applications will be reviewed in the order they are received.
(2) The National Coordinator is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(b) *Application deficiencies.*
(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the National Coordinator may issue a deficiency notice to the applicant.
(2) If the National Coordinator determines that deficiencies in the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.*
(1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request from the National Coordinator an extension for good cause of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.
(2) In order for an applicant to continue to be considered for ONC–ACB status, the applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice, unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.
(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.
(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant cannot reapply for ONC–ACB status for a period of six months from the date of the denial notice. An applicant may request reconsideration of this decision in accordance with § 170.535.

(d) *Satisfactory application.*
(1) An application will be deemed satisfactory if it meets all the application requirements, as determined by the National Coordinator.
(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC–ACB status.
(3) Once notified by the National Coordinator of its successful achievement of ONC–ACB status, the applicant may represent itself as an ONC–ACB and begin certifying health information technology consistent with its authorization.

§ 170.535 ONC–ACB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC–ACB status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National

Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual error(s) it believes can account for the denial. If the National Coordinator does not receive the applicant's reconsideration request within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) *Decision.*

(1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's determination and the applicant's successful achievement of ONC–ACB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify factual errors or that the correction of the factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.540 ONC–ACB status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC–ACBs, including the date each was authorized and the type(s) of certification each has been authorized to perform.

(b) *Representation.* Each ONC–ACB must prominently and unambiguously identify the scope of its authorization on its Web site and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program.

(c) *Renewal.* An ONC–ACB is required to renew its status every three years. An ONC–ACB is required to submit a renewal request, containing any updates to the information requested in § 170.520, to the National Coordinator 60 days prior to the expiration of its status.

(d) *Expiration.* An ONC–ACB's status will expire three years from the date it was granted by the National Coordinator unless it is renewed in accordance with paragraph (c) of this section.

§ 170.545 Complete EHR certification.

(a) When certifying Complete EHRs, an ONC–ACB must certify in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ACB must provide the option for a Complete EHR to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC–ACB may provide the option for and perform gap certification of previously certified Complete EHRs.

(d) *Inherited certified status.* An ONC–ACB must accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC–ACB must review an attestation submitted by the developer of the Complete EHR to determine whether any change in the newer version has adversely affected the Complete EHR's capabilities for which certification criteria have been adopted.

(2) An ONC–ACB may grant certified status to a newer version of a previously certified Complete EHR if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

(e) An ONC–ACB that has been authorized to certify Complete EHRs is also authorized to certify all EHR Modules under the permanent certification program.

§ 170.550 EHR Module certification.

(a) When certifying EHR Module(s), an ONC–ACB must certify in accordance with the applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ACB must provide the option for an EHR Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC–ACB may provide the option for and perform gap certification of previously certified EHR Module(s).

(d) An ONC–ACB may provide an updated certification to a previously certified EHR Module(s).

(e) *Privacy and security certification.* EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) *Inherited certified status.* An ONC–ACB must accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module(s), an ONC–ACB must review an attestation submitted by the developer(s) of the EHR Module(s) to determine whether any change in the newer version has adversely affected the EHR Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC–ACB may grant certified status to a newer version of a previously certified EHR Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

§ 170.553 Certification of health information technology other than Complete EHRs and EHR Modules.

An ONC–ACB authorized to certify health information technology other than Complete EHRs and/or EHR Modules must certify such health information technology in accordance with the applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

§ 170.555 Certification to newer versions of certain standards.

(a) ONC–ACBs may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part if the Secretary has accepted a newer version of an adopted minimum standard.

(b) *Applicability of an accepted newer version of an adopted minimum standard.*

(1) ONC–ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the **Federal Register** with a newer version.

(2) Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

§ 170.557 Authorized certification methods.

An ONC–ACB must provide remote certification for both development and deployment sites.

§ 170.560 Good standing as an ONC–ACB.

An ONC–ACB must maintain good standing by:

(a) Adhering to the Principles of Proper Conduct for ONC–ACBs;

(b) Refraining from engaging in other types of inappropriate behavior, including an ONC–ACB misrepresenting the scope of its authorization, as well as an ONC–ACB certifying Complete EHRs and/or EHR Module(s) for which it does not have authorization; and

(c) Following all other applicable Federal and State laws.

§ 170.565 Revocation of ONC–ACB status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC–ACB's status for committing a Type-1 violation. Type-1 violations include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the permanent certification program, a program administered by HHS or any program administered by the Federal government.

(b) *Type-2 violations.* The National Coordinator may revoke an ONC–ACB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute noncompliance with § 170.560.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC–ACB may no longer be in compliance with § 170.560, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC–ACB requesting that the ONC–ACB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC–ACB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC–ACB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC–ACB during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC–ACB confirming this determination.

(iii) If the National Coordinator determines that the ONC–ACB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the noncompliance notification, then the National Coordinator may propose to revoke the ONC–ACB's status.

(c) *Proposed revocation.*

(1) The National Coordinator may propose to revoke an ONC–ACB's status if the National Coordinator has reliable evidence that the ONC–ACB has committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC–ACB's status if, after the ONC–ACB has been notified of a Type-2 violation, the ONC–ACB fails to:

(i) To rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the noncompliance notification within the specified timeframe under paragraph (b)(2) of this section.

(d) *Suspension of an ONC–ACB's operations.*

(1) The National Coordinator may suspend the operations of an ONC–ACB under the permanent certification program based on reliable evidence indicating that:

(i) The ONC–ACB committed a Type-1 or Type-2 violation; and

(ii) The continued certification of Complete EHRs, EHR Module(s), and/or other types of HIT by the ONC–ACB could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) of this section have been met, an ONC–ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC–ACB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC–ACB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC–ACB's written response or if the ONC–ACB fails to submit a written response within the timeframe specified in paragraph (d)(3) of this section:

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC–ACB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with § 170.565(c) and suspend the ONC–ACB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC–ACB's receipt of a notice of suspension.

(e) *Opportunity to respond to a proposed revocation notice.*

(1) An ONC–ACB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC–ACB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC–ACB and reach a decision.

(f) *Good standing determination.* If the National Coordinator determines that an ONC–ACB's status should not be revoked, the National Coordinator will notify the ONC–ACB's authorized representative in writing of this determination.

(g) *Revocation.*

(1) The National Coordinator may revoke an ONC–ACB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC–ACB in response to the proposed revocation notice; or

(ii) The ONC–ACB does not respond to a proposed revocation notice within the specified timeframe in paragraph (e)(1) of this section.

(2) A decision to revoke an ONC–ACB's status is final and not subject to further review unless the National

Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation.*

(1) The revocation of an ONC–ACB is effective as soon as the ONC–ACB receives the revocation notice.

(2) A certification body that has had its ONC–ACB status revoked is prohibited from accepting new requests for certification and must cease its current certification operations under the permanent certification program.

(3) A certification body that has had its ONC–ACB has its status revoked for a Type-1 violation, is not permitted to reapply for ONC–ACB status under the permanent certification program for a period of 1 year.

(4) The failure of a certification body that has had its ONC–ACB status revoked to promptly refund any and all fees for certifications of Complete EHRs and EHR Module(s) not completed will be considered a violation of the Principles of Proper Conduct for ONC–ACBs and will be taken into account by the National Coordinator if the certification body reapplies for ONC–ACB status under the permanent certification program.

§ 170.570 Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s).

(a) The certified status of Complete EHRs and/or EHR Module(s) certified by an ONC–ACB that had its status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC–ACB.

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC–ACB, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC–ACB's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that Complete EHRs and/or EHR Module(s) were improperly certified by the former ONC–ACB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR Module(s) were improperly certified, the certification status of affected Complete EHRs and/or EHR Module(s) would only remain intact for 120 days after the National Coordinator publishes the notice. The certification status of affected Complete EHRs and/or EHR Module(s) can only be maintained thereafter by being re-certified by an ONC–ACB in good standing.

§ 170.599 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH·1211, Geneve 20, Switzerland, telephone +41–22–749–01–11, *http://www.iso.org.*

(1) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, IBR approved for § 170.503.

(2) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 170.503.

(3) [Reserved]

Dated: December 14, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–33174 Filed 1–3–11; 4:15 pm]

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H.R. 81/P.L. 111–348
To amend the High Seas Driftnet Fishing Moratorium Protection Act and the Magnuson-Stevens Fishery Conservation and Management Act to improve the conservation of sharks. (Jan. 4, 2011; 124 Stat. 3668)

H.R. 628/P.L. 111–349
To establish a pilot program in certain United States district courts to encourage enhancement of expertise in patent cases among district judges. (Jan. 4, 2011; 124 Stat. 3674)

H.R. 1107/P.L. 111–350
To enact certain laws relating to public contracts as title 41, United States Code, ''Public Contracts''. (Jan. 4, 2011; 124 Stat. 3677)

H.R. 1746/P.L. 111–351
Predisaster Hazard Mitigation Act of 2010 (Jan. 4, 2011; 124 Stat. 3863)

H.R. 2142/P.L. 111–352
GPRA Modernization Act of 2010 (Jan. 4, 2011; 124 Stat. 3866)

H.R. 2751/P.L. 111–353
FDA Food Safety Modernization Act (Jan. 4, 2011; 124 Stat. 3885)

H.R. 4445/P.L. 111–354
Indian Pueblo Cultural Center Clarification Act (Jan. 4, 2011; 124 Stat. 3974)

H.R. 4602/P.L. 111–355
To designate the facility of the United States Postal Service located at 1332 Sharon Copley Road in Sharon Center, Ohio, as the ''Emil Bolas Post Office''. (Jan. 4, 2011; 124 Stat. 3975)

H.R. 4748/P.L. 111–356
Northern Border Counternarcotics Strategy Act of 2010 (Jan. 4, 2011; 124 Stat. 3976)

H.R. 4973/P.L. 111–357
National Wildlife Refuge Volunteer Improvement Act of 2010 (Jan. 4, 2011; 124 Stat. 3979)

H.R. 5116/P.L. 111–358
America COMPETES Reauthorization Act of 2010 (Jan. 4, 2011; 124 Stat. 3982)

H.R. 5133/P.L. 111–359
To designate the facility of the United States Postal Service located at 331 1st Street in Carlstadt, New Jersey, as the ''Staff Sergeant Frank T. Carvill and Lance Corporal Michael A. Schwarz Post Office Building''. (Jan. 4, 2011; 124 Stat. 4050)

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